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(54) **Handle For Manipulating A Catheter Tip, Catheter System And Medical Insertion System For Inserting A Self-Expandable Heart Valve Stent**

(57) This invention is directed to a handle (70) for manipulating a catheter tip (10) of a catheter insertion system (100), with which a self-expandable heart valve stent (150) can be inserted into the body of a patient. The invention further concerns a catheter system (30) of a catheter insertion system (100) as well as a catheter insertion system (100) itself. The proposed catheter insertion system (100) is designed to enable the implantation

of a heart valve prosthesis (160) attached to a heart valve stent (150) in the optimum implantation location in a sequence of events defined before the intervention. For this purpose, the catheter insertion system (100) comprises the handle (70) for manipulating the catheter tip (10) of the catheter insertion system (100), wherein the handle (70) comprises means (71, 81) that prescribe a pre-set sequence of steps such that each subsequent step is inhibited until the preceding step has been completed.

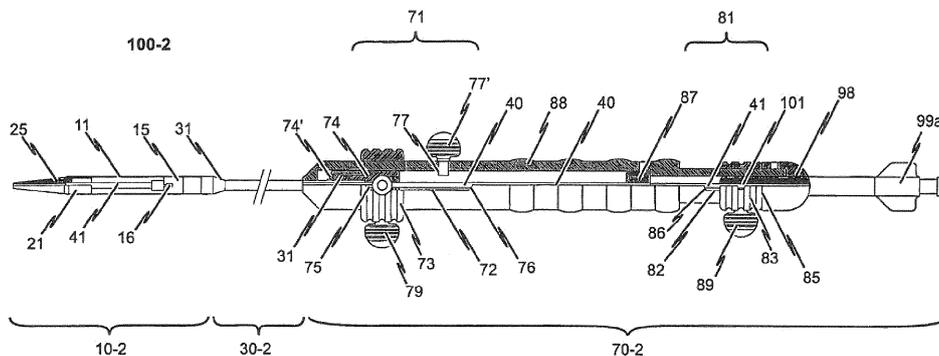


Fig. 16

## Description

**[0001]** The present invention concerns a handle for manipulating a catheter tip of a medical insertion system, with which a self-expandable heart valve stent can be inserted into the body of a patient. The invention further concerns a catheter system of a medical insertion system as well as a medical insertion system itself. The invention furthermore concerns a medical device for treatment of a heart valve defect, in particular a heart valve insufficiency or a heart valve stenosis in a patient.

**[0002]** In medical technology, there has been an endeavour over a long period to close a heart valve defect, such as an aortic valve insufficiency or an aortic valve stenosis, non-surgically by means of a trans-arterial interventional access by catheter, thus technically without an operation. Various insertion systems and stent systems have been proposed, with different advantages and disadvantages, which in part can be introduced into the body of a patient trans-arterially by means of a catheter insertion system, though a specific system has not prevailed up to the present.

**[0003]** The term used here "heart valve stenosis and/or heart valve insufficiency" shall generally be understood here as a congenital or acquired functional disorder of one or several heart valves. A valve defect of this type can affect each of the four heart valves, whereby the valves in the left ventricle (aortic and mitral valve) are certainly more frequently affected than those of the right heart (pulmonary and tricuspid valve). The functional disorder can result in narrowing (stenosis) or inability to close (insufficiency) or a combination of the two (combined cardiac defect). The present invention relates to a handle and a catheter system of an insertion system, an insertion system for inserting a heart valve stent and a medical device for treatment of a heart valve defect of this type.

**[0004]** With all known interventional systems for implantation of a heart valve prosthesis, a self-expanding stent system is moved trans-arterially to an insufficient heart valve. A stent system of this type consists, for example, of a self-expanding anchoring support (also termed "heart valve stent" or "stent" in the following), to which the actual heart valve prosthesis is fastened, preferably at the proximal retaining region of the anchoring support.

**[0005]** In the medical devices previously known from the state-of-the-art, however, it has become apparent that the implantation procedure of a stent system to which the heart valve prosthesis is attached is relatively complicated, difficult and expensive. Apart from the complicated implantation of the heart valve prosthesis as a replacement for an insufficient native heart valve, there is the fundamental risk of incorrect positioning of the stent or heart valve prosthesis with the medical devices used up to the present, which cannot be corrected without more extensive operative intervention.

**[0006]** The problem addressed by the present inven-

tion is the fact that medical technology does not currently offer any insertion system for trans-apical or trans-arterial or trans-femoral implantation of a self-expandable heart valve stent with a heart valve prosthesis attached to it in which, on the one hand, the insertion system enables a minimally invasive implantation of the heart valve prosthesis in a predictable manner and, on the other, dispensing with the need to use a heart-lung machine during the operation on the anaesthetized patient. Consequently the operative intervention can be designed to be especially cost-effective and, in particular, to reduce the physical and mental stress on the patient. In particular, there is a lack of a medical device for implantation of heart valve prostheses that can also be used for patients on whom, due to their age, an operation cannot be carried out without the aid of a heart-lung machine.

**[0007]** Because of the increasing number of patients requiring treatment, there is also a growing need for an insertion system with which a minimally invasive intervention can be made on a patient for treatment of a heart valve stenosis and/or heart valve insufficiency in a precisely predictable way, whereby the success of the operation is in particular no longer significantly dependent on the skill and experience of the heart surgeon or radiologist carrying out the treatment.

**[0008]** This situation also applies to operations in which heart valve prostheses with stents systems are implanted with the aid of a so-called balloon catheter system.

**[0009]** It is also regarded as problematic that, when using systems already known from the state-of-the-art by means of which a heart valve prosthesis can be implanted in the body of the patient with minimal invasiveness, incorrect positioning of the heart valve prosthesis or the associated heart valve stent can frequently only be avoided when the heart surgeon or radiologist is especially experienced. It is indeed known, for example, to insert a heart valve stent with a heart valve prosthesis attached to it into the body of a patient as far as the heart via the aorta, whereby self-expansion of the heart valve stent is initiated by external manipulation when the implantation location is reached, which should lead to a secure anchorage and precise positioning of the heart valve prosthesis; such heart valve stents cannot usually be removed in a simple way, however, and their position cannot usually be corrected once the stent has expanded.

**[0010]** Accordingly, there is basically a risk with the known systems that if, for example, the self-expansion of the heart valve stent with the attached heart valve prosthesis is initiated in a non-optimum position, due to a slip by the doctor carrying out the treatment or other circumstances, this position can only be corrected appropriately by means of a major, in particular operative, intervention, which must frequently be carried out on the open heart.

**[0011]** For example, a heart valve stent for a heart valve prosthesis is described in document WO 2004/019825 A1. With this heart valve stent, proximal-end support arches or hoops and positioning arches or

hoops are provided, which can be inserted into the pockets of the native heart valve of a patient so that the heart valve stent can be positioned by means of the support hoops. Additional so-called commissural hoops can also be formed on the known heart valve stent which, together with the support arches, clamp parts of the old heart valve once the stent has unfolded to that the stent can be positioned and anchored as a result of this clamping action.

**[0012]** Although the support arches provided on the anchoring stent enable improved positioning of the heart valve prosthesis to be implanted, there is nevertheless still a risk of incorrect implantation and of the heart valve prosthesis being incapable of functioning correctly or functioning but unsatisfactorily. For example, it may be found during the intervention that the heart valve prosthesis or the heart valve stent is not optimally dimensioned for the patient. In such cases, even if only the respective proximal support or positioning arches of the stent are in their expanded state, removal (explantation) or repositioning of the heart valve stent with the heart valve prosthesis is no longer possible and there exists an increased mortality risk for the particular patient.

**[0013]** The aortic arch in the human body represents a further problem for such interventions, since it has to be accessed during insertion through the aorta. When this is done, the catheter tip and the respective catheter must undergo a change of direction of approx. 180° over a relatively small radius, usually about 50 mm, without causing injury or damage to the vessel wall.

**[0014]** Starting from this problem, the objective of the invention is to propose a catheter insertion system, for inserting a self-expandable heart valve stent into the body of a patient and for positioning the stent at a desired implantation site, that is designed to enable the implantation of a heart valve prosthesis attached to a heart valve stent in the optimum implantation location in a sequence of events defined before the intervention.

**[0015]** Secondly, the objective is to propose a medical device for treatment of a heart valve stenosis and/or heart valve insufficiency, comprising a catheter insertion system and a self-expandable heart valve stent mounted in the catheter tip of the insertion system and which is designed to reduce the risk to the patient on implantation of the heart valve prosthesis.

**[0016]** According to the first aspect, the invention resides in a handle for manipulating a vascular insertion system, wherein the handle comprises means that prescribe a pre-set sequence of steps such that each subsequent step is inhibited until the preceding step has been completed. Ideally the handle includes means that prescribe or enforce a pre-set sequence of steps for staged release of the stent.

**[0017]** The term "pre-set" refers to steps that have been set of fixed in advance of operation of the vascular insertion system and handle. The steps of operation are pre-conditioned such that one step must be completed before the next step can be effected. A predetermined series of steps reduces the risk of incorrect positioning

and requires less skill and expertise on the part of whomsoever performs the procedure. Thus, the sequence of events which can be determined beforehand relates to those events or steps of the operation which depend on and, for example, may be controlled by, the insertion system and handle.

**[0018]** In this way, a catheter tip of the insertion system may be manipulated especially reliably with the handle and a heart valve stent may be introduced in a particularly simple but nevertheless reliable way into the body of a patient and optimally positioned at the implantation site in the heart.

**[0019]** While it will be appreciated that such a handle may be applied to any catheter system for which, for example, delivery, accurate positioning and/or control of medical devices is required, for the purposes of the present invention, the handle is used in conjunction with a vascular insertion system for introducing a stent into a patient's body and for positioning the stent at a desired implantation site. Whilst the term "vascular" refers to the blood vessels of the body including both veins and arteries, in a preferred embodiment the system is for transarterial delivery using the arteries, although it is conceivable that in other embodiments transvenous delivery via a vein could be used.

**[0020]** In particular, the vascular insertion system comprises a catheter and a tip. The distal end of the catheter is attached to the handle and the proximal end is attached to the tip. In a preferred embodiment, the tip accommodates the stent.

**[0021]** In relation to the handle, the objective forming the basis of the invention is solved according to the invention in that the handle has at least one first and one second operating means with which the catheter tip of an insertion system may be appropriately manipulated so that a self-expandable stent housed in the catheter tip may be released from the catheter tip in steps or in a previously defined or definable sequence of events.

**[0022]** In relation to the catheter system, the problem forming the basis of the invention is solved according to the invention in that the catheter system has first and second force transmission means. These force transmission means are at the proximal end region of the catheter system, i.e. at the end region of the catheter system nearest the heart, and can be connected to a catheter tip in which a heart valve stent is mounted or can be mounted. In detail, the force transmission means are designed to manipulate the first and second housing portions of the catheter tip so that a self-expandable stent housed in the catheter tip may be released from the catheter tip in steps or in accordance with a previously defined or definable sequence of events. Then at the distal end region of the catheter system, i.e. at the end region of the catheter system which is facing away from the heart, the force transmission means may be connected to first and second operating means of a handle of the type referred to above.

**[0023]** In relation to the insertion system, the problem

forming the basis of the invention is solved in that the insertion system has a catheter system of the type referred to above, by means of which the cardiac valve stent can be introduced into the body of the patient in its folded-up state. The insertion system further has a catheter tip provided at the proximal end region of the catheter system, i.e. adjacent to the heart, with first and second manipulable housing portions. Furthermore, the insertion system has a handle of the type referred to above at the distal end region of the catheter system, i.e. at the end region of the catheter system which is remote from the heart and the catheter tip. The first and second housing portions of the catheter tip may be manipulated appropriately with the handle so that the self-expandable stent accommodated in the catheter tip may be released from the catheter tip in a previously defined or definable sequence of events.

**[0024]** In relation to the medical device, the problem forming the basis of the invention is solved in that the device has an insertion system of the type referred to above together with a self-expandable cardiac valve stent accommodated in the catheter tip of the insertion system.

**[0025]** Further arrangements and advantageous embodiments of the handle in accordance with the invention, the catheter system of the invention and the insertion system of the invention together with the insertion system in accordance with the invention are specified in the respective dependent patent claims.

**[0026]** An insertion system can be implemented with the present invention for inserting a stent into the body of a patient, whereby the insertion system exhibits the following:

- a catheter system, by means of which a self-expandable cardiac valve stent (also simply termed "stent" in the following) can be introduced in its folded-up state into the body of a patient;
- a catheter tip provided at the proximal end region of the catheter system, in which the stent can be mounted;
- a handle at the distal end region of the catheter system, with which the catheter tip can be manipulated.

**[0027]** Preferably the insertion system according to the invention comprises a catheter tip, as is described, for example, in the international Patent Application No. PCT/EP2007/061117. The catheter tip has a region termed "stent holder" in the following, by means of which the stent can be attached to the catheter tip. In detail, the stent holder is used for releasably fixing at least one region of the stent in the catheter tip.

**[0028]** Furthermore it is possible in a preferred embodiment of the catheter tip for this to have first and second housing portions that may be manipulated with the handle. These housing portions are used for accommodating

specific portions of the stent. The first housing portion is used for accommodating first functional components of the stent, for example retaining hoops of the stent (or alternatively positioning hoops of the stent), while the second housing portion is used for accommodating the second functional components of the stent, for example, positioning hoops of the stent (or alternatively for accommodating retaining hoops of the stent).

**[0029]** In relation to the handle provided for the insertion system, it is preferably provided that, on one hand, the first operating means cooperate with the first housing portion of the catheter tip so that, on actuation of the first operating means, a previously definable longitudinal displacement of the first housing portion may be effected relative to the stent holder and, on the other hand, the second operating means cooperates with the second housing portion of the catheter tip so that a previously definable longitudinal displacement of the second housing portion may be affected relative to the stent holder.

**[0030]** With regard to the treatment of a heart valve stenosis and/or heart valve insufficiency in a patient, the objective referred to above is achieved according to the invention with the aid of a medical device, whereby this medical device comprises an insertion system of the type proposed by the invention and a self-expandable heart valve stent accommodated in the catheter tip of the insertion system. While it is accommodated in the catheter tip of the insertion system, the stent adopts a first previously definable configuration. Outside the catheter tip or in the implanted state, however, the stent exists in a second previously definable configuration. The first configuration of the stent corresponds to the folded-up state, while the stent exists in its expanded state in the second configuration.

**[0031]** A heart valve stent is used with the medical device, as described for example in the European Patent Application No. 07 110 318 or in the European Patent Application No. 08 151 963. In a preferred embodiment of the medical device according to the invention, a heart valve stent is accordingly used which exhibits the following:

- a first retaining region, to which a heart valve prosthesis can be attached;
- an opposing, second retaining region with at least one retaining element, for example in the form of retaining eyes or in the form of retaining heads, whereby at least one retaining element of the stent can be put in releasable engagement with the stent holder of the catheter tip forming part of the insertion system;
- at least one retaining hoop, to which a heart valve prosthesis can be fastened; and
- at least one and preferably three positioning hoops, which are designed to engage in pockets of the na-

tive heart valve in the implanted state of the stent, thus to enable automatic positioning of the stent in the aorta of the patient.

**[0032]** The advantages that can be obtained with the proposed insertion system, which comprises the handle of the invention, the catheter system of the invention together with the catheter tip, are obvious. In particular, an insertion system is proposed, with which a self-expandable heart valve stent with a heart valve prosthesis attached to this stent can be advanced to the implantation site in a particularly simple way, for example via the aorta of a patient being treated (trans-arterially or trans-femorally) or from the apex of the heart (trans-apically). Preferably, during trans-arterial or trans-femoral access by the catheter system, the whole free cross-section available within the aorta is not completely filled up, since the catheter tip provided at the proximal end region of the catheter system, in which the stent can be accommodated with the heart valve prosthesis, can be made sufficiently small with respect to its external diameter.

**[0033]** The self-expandable heart valve stent with the heart valve prosthesis attached to it can be accommodated temporarily during implantation in the folded-up state in the catheter tip of the insertion system, which is provided at the proximal end region of the catheter system. The catheter system may be of a length sufficient to allow the catheter tip provided at the proximal end region of the catheter system to be guided through the aorta to the patient's heart by insertion at the patient's groin.

**[0034]** However, the insertion system of the invention is not only suitable for a trans-arterial or trans-femoral access, but can also be used trans-apically, i.e. from the apex of the heart, to insert and position the heart valve stent with the heart valve prosthesis attached to it into the body of the patient and to place it percutaneously, orthotopically in vivo, so that the heart valve prosthesis can assume the function of an insufficient or stenosed native heart valve. As will be explained, an insertion system that is designed for trans-apical access can have a shorter catheter system compared with that for trans-arterial access.

**[0035]** To enable the stent accommodated in the catheter tip to be inserted into the body of the patient with the aid of the catheter system and, where required, with the aid of a further insertion wire (guide wire), it is preferably provided that the catheter tip has a mounting (stent holder) for releasably fixing of at least the second retaining region of the stent and mounting regions for accommodating the first retaining region with the positioning hoops and the retaining hoops together with, where required, the heart valve prosthesis fastened to the retaining hoops. Further it is preferable for the handle to be provided at the distal end the region of the catheter system, so that the catheter tip and, in particular, the respective housing portions of the catheter tip can be manipulated and moved in a directed manner.

**[0036]** In particular, a radial or also lateral movement

of the catheter tip and/or the individual housing portions of the catheter tip can be obtained. As a result of this selective movement of the individual components of the catheter tip, individual components (positioning hoops, retaining hoops) of the heart valve stent can be sequentially released in accordance with a predictable sequence of events, so that the implantation of the heart valve prosthesis can take place with the necessary positioning and anchoring.

**[0037]** Specifically, it is provided in the insertion system in accordance with the invention that the catheter tip has the housing portions already referred to, whereby the handle has at least a first operating means associated with the first housing portion and a second operating means associated with the second housing portion. The first operating means cooperates with the first housing portion of the catheter tip so that, on actuation of the first operating means, a previously definable longitudinal displacement of the first housing portion can be effected relative to the stent holder of the catheter tip. In an analogous way, the second operating means cooperates with the second housing portion of the catheter tip so that, on actuation of the second operating means, a previously definable longitudinal displacement of the second housing portion can be effected relative to the stent holder of the catheter tip.

**[0038]** The respective co-operation of the operating means forming part of the handle with the associated housing portions of the catheter tip can be achieved, for example, with the aid of suitable force transmission means of the catheter system.

**[0039]** By providing the appropriate operating means in the handle, on the one hand, and the first and second housing portions in the catheter tip on the other, the respective housing portions of the catheter tip can be manipulated selectively and can be moved according to a previously definable sequence of events.

**[0040]** The proposed insertion system is therefore not only suitable to introduce the stent housed in the catheter tip provided at the proximal end of the catheter system into the body of the patient at the implantation site with a suitable radial and/or lateral movement, with the aid of the catheter system, but also to obtain a sequential release of the respective functional components (positioning hoops, retaining hoops) of the stent by directed and previously definable movements of the housing portions of the catheter tip, so that the implantation of the heart valve prosthesis with the heart valve stent may take place in a particularly suitable but nevertheless effective manner.

**[0041]** In particular, it is possible that, for example, release of the positioning hoops of the heart valve stent are released by a twisting and/or a lateral movement in the proximal or distal direction of one of the two housing portions of the catheter tip, while the retaining hoops of the stent are still held in the folded-up form by the other housing portion of the catheter tip. The retaining hoops of the stent can then be released by a corresponding

manipulation of the other housing region of the catheter tip.

**[0042]** To ensure that a stent mounted in the catheter tip with a heart valve prosthesis attached to the retaining hoops of the stent can be implanted trans-arterially or trans-femorally, in other words coming via the aorta, it is proposed by the insertion system in accordance with the invention that the first housing portion of the catheter tip is in the form of a so-called "stent sheath". The stent sheath is a sleeve-like housing portion, whose opening points in the direction of the proximal end tip of the catheter tip. When the catheter tip is actually inserted into the body of the patient, the catheter tip is in its so-called "closed state". In this closed state, these stent sheath forms the outer circumferential surface of the catheter tip, while the stent is housed in its folded-up state in the interior of the stent sheath.

**[0043]** When the first operating means of the handle is actuated, with the insertion system designed for trans-arterial or trans-femoral access, the first housing portion of the catheter tip can be moved relative to the stent holder in the longitudinal direction of the catheter tip. In detail, to open the catheter tip or to release a stent housed in the catheter tip, the movement of the first housing portion takes place in the direction of the handle, away from the proximal end tip of the catheter tip.

**[0044]** With the insertion system designed for trans-arterial or trans-femoral access, it is further provided that the second housing portion of the catheter tip is in the form of a so-called "stent funnel". The stent funnel is a sleeve-like housing portion, which is connected to the proximal end tip of the catheter tip and which has its opening pointing in the direction of the distal end region of the catheter tip. The retaining hoops of the stent and the heart valve prosthesis, where fastened to the retaining hoops, can be housed in the interior of the stent funnel. The stent funnel fits telescopically into the stent sheath when the catheter tip is in the closed state. The positioning hoops of the stent are then located between the outer circumferential surface of the stent funnel and the inner circumferential surface of the stent sheath.

**[0045]** When the second operating means of the handle is actuated, with the insertion system designed for trans-arterial or trans-femoral access, the second housing portion of the catheter tip can also be moved relative to the stent holder in the longitudinal direction of the catheter tip. In detail, to release a stent housed in the catheter tip, the second housing portion is moved together with the proximal end tip of the catheter tip in the proximal direction, i.e. away from the handle.

**[0046]** The insertion system designed for trans-arterial or trans-femoral access is therefore suitable for inserting a heart valve stent with a heart valve prosthesis attached to it, trans-arterially or trans-femorally into the body of the patient; for example, the catheter system of the insertion system is inserted with the catheter tip located at the proximal end of the catheter system via puncture of the A. femoris communis (inguinal artery).

**[0047]** The catheter tip and, optionally, also the catheter system of the insertion system, are advanced, preferably under angiographic (vessel display) and echocardiographic (ultrasonic) control into the heart valve position. The actual implantation of the heart valve then follows, in which, by means of previously definable manipulations of the associated housing portions of the catheter tip, which can be effected with the respective operating actuating means of the handle, the individual components of the heart valve stent mounted in the catheter tip are released.

**[0048]** Alternatively, however, the insertion system in accordance with the invention is also suitable for a trans-apical access, in which case - approaching from the apex of the heart - the catheter tip of the catheter system is pushed, for example, through the left ventricle to the aortic valve. With an appropriately modified catheter tip, an analogous implantation of the heart valve stent with the heart valve prosthesis is possible here.

**[0049]** In detail, with the insertion system designed for trans-apical access, it is provided that the first housing portion of the catheter tip is in the form of a stent sheath, which is connected to the proximal end tip of the catheter tip and has an opening pointing in the direction of the distal end region of the catheter tip. As with the insertion system designed for trans-arterial or trans-femoral access, the stent sheath for the insertion system designed for trans-apical access forms the outer circumferential surface of the catheter tip, when this is in the closed state.

**[0050]** When the first operating means of the handle is actuated, with the insertion system designed for trans-apical access, the first housing portion of the catheter tip can be moved relative to the stent holder in the longitudinal direction of the catheter tip, whereby the movement of the first housing portion takes place in the proximal direction, thus away from the handle, to open the catheter tip or to release a stent housed in the catheter tip.

**[0051]** With the insertion system designed for trans-apical access, the second housing portion of the catheter tip is in the form of a stent funnel which has its opening pointing in the direction of the proximal end tip of the catheter tip. Once again, the retaining hoops of the stent and the heart valve prosthesis, where fastened to the retaining hoops, can be mounted in the interior of the stent funnel, while the stent funnel fits telescopically into the stent sheath when the catheter tip is in the closed state, whereby the positioning hoops of the stent are located between the outer circumferential surface of the stent funnel and the inner circumferential surface of the stent sheath.

**[0052]** When the second operating means of the handle is actuated, with the insertion system designed for trans-apical access, the second housing portion of the catheter tip can also be moved relative to the stent holder in the longitudinal direction of the catheter tip. Specifically, to release a stent housed in the catheter tip, the second housing portion is moved in the direction of the proximal end tip of the catheter tip.

**[0053]** Irrespective of whether the insertion system is designed for a trans-arterial and trans-femoral access or a trans-apical access, the insertion system of the invention exhibits a catheter tip with a first housing portion, for example for housing of the retaining hoops of the stent (as first functional components of the stent) and a second housing portion, for example for housing of the positioning hoops of the stent (as second functional components of the stent), whereby the two housing portions can be manipulated by actuation of operating means provided in the handle, in accordance with a previously definable sequence of events, and as a result the individual components of the heart valve stent can be released.

**[0054]** In relation to the catheter system used with the insertion system, it is preferably provided that this has an outer catheter, in which at least one inner catheter is accommodated. The outer circumferential surface of the outer catheter then forms the outer shell of the catheter system. Preferably the outer catheter and the at least one inner catheter then respectively act as force transmission means. In the insertion system, the force transmission means are connected at the distal end region of the catheter system with the actuating means of the handle and are connected at the proximal end region of the catheter system to the housing portions of the catheter tip. The outer catheter and the at least one inner catheter have the function of transmitting compressive and tensile forces from the corresponding operating means of the handle to the corresponding housing portions of the catheter tip. It is preferable that the outer catheter and the at least one inner catheter are each designed so that their length virtually does not change even under compressive or tensile stress.

**[0055]** In particular, with the insertion system designed for trans-arterial or trans-femoral access, the catheter system should be designed so that it is both kink-resistant and flexible such that a bending radius of up to 4 cm, and preferably up to 3 cm, can be realised, at least at the proximal end region of the catheter system.

**[0056]** It is possible, for example, that a material of suitable wall thickness is provided for the outer catheter and the at least one inner catheter to produce the required kink resistance, on the one hand, and flexibility, on the other. This allows the catheter system of the insertion system designed for trans-arterial or trans-femoral access to have at least one flexible region at the proximal end to make it possible for it to follow the natural course of the A. iliaca and the A. femoralis at the initial points with a bend of up to 30° without difficulty. The values cited above relating to the realisable bending radius can naturally be selected in another range, though it should be taken into account that the bending radius of the aortic arch, which must be negotiated with a trans-arterial access, is approximately 4 cm in a human.

**[0057]** To ensure that, as far as possible, the responsible operator has all the latitude required to move the catheter tip forward into the implantation site during the insertion procedure when using the insertion system de-

signed for trans-arterial or trans-femoral access, in a preferred variant of the insertion system the catheter system has a flexural joint, which can be deflected with the aid of a further (third) actuating means. Preferably, the handle comprises a wheel, for example, or similar as third actuating means to enable manipulation of the flexural link region.

**[0058]** In relation to the deflection device that can be implemented with the flexural link zone, it is possible, for example, to provide a further device for force transmission inside the catheter system or the outer catheter forming part of the catheter system, for example in the form of a control wire which at one end cooperates with the flexural link zone and, on the other, is connected to the third actuating means of the handle. This device for force transmission can be guided inside the outer catheter forming part of the catheter system, for example, and either act on the flexural link or on the catheter tip itself, to allow a specific effect on the curvature of the flexural link zone to be obtained.

**[0059]** In particular, a specific curvature of the flexural link zone provided in the tube system may be achieved by exerting tensile forces by means of the device for force transmission, for example during implantation when navigating the aortic arch. Draw cables or draw wires as the device for force transmission can be guided through the internal hollow outer catheter to the proximal end region of the flexural link zone formed integrally, for example, in the catheter system and can be fastened there. Preferably, the force application points of two such draw cables or draw wires are diametrically opposed. Thus a specific effect can be obtained of the curvature of the flexural link zone and consequently of the catheter system by exerting a tensile force by means of one of the existing devices for force transmission, when the catheter system with the flexural link zone is, for example, pushed through the aortic arch or drawn out of it on completion of implantation.

**[0060]** However, it is of course also possible to form the flexural link zone as a link chain, in which case the individual elements are connected to one another by individual joints. The individual joints may positively engage in respective adjacent elements and may be so configured that a curvature of the flexural link zone by more than 180° can be maintained with an appropriate bending radius. The bending radius should be selected so that it is at least possible to obtain the radius of the aortic arch.

**[0061]** It is also possible to obtain the function of the link chain with an integral, one-piece tube in which the tube has slits at specific spacings that ensure the desired flexibility, at least in the preferred direction.

**[0062]** In a preferred embodiment of the flexural link zone, it is possible for this to be in the form of a link chain whereby the individual elements are connected together by means of individual links and whereby the individual links are also formed on the individual elements of the link chain in pairs diametrically opposite each other and

are arranged parallel to the axis of rotation of the bendable region.

**[0063]** To enable the catheter tip to be moved radially, in particular for the purpose of precise positioning of a heart valve stent advanced with the insertion system to the implantation location on the heart, it is provided in a preferred embodiment of the insertion system designed for trans-apical access that the catheter system and the respective couplings of the catheter system to the catheter tip on one side and to the handle on the other side are configured so that it is possible to twist the catheter tip about the longitudinal axis of the of the catheter tip by turning the handle and/or the catheter system. In particular, the catheter system and the respective couplings of the catheter system to the catheter tip and to the handle should exhibit a previously definable, preferably small, delay in reaction, due to a torque introduced by means of the handle.

**[0064]** As already indicated, it is preferably provided for the insertion system according to the present invention that the catheter tip has a stent holder with retaining elements. The stent holder with the retaining elements is used to anchor the second retaining region of the stent during the insertion procedure and during positioning of this stent in the implantation location at the catheter tip. It would be possible to configure the retaining elements of the stent holder as projecting elements which can be brought into engagement with corresponding retaining rings having complementary configuration at the second retaining region of the stent for releasably fixing the second retaining region of the stent.

**[0065]** In a particularly preferred embodiment of the stent holder forming part of the catheter tip it is provided, however, that the stent holder has an essentially cylindrical body, whose axis of symmetry lies on the longitudinal axis of the catheter tip. Several uniformly spaced recesses are formed on the cylindrical body at the distal-side end region of the body in the insertion system designed for trans-apical access, and at the proximal-side end region of the cylindrical body in the insertion system designed for trans-femoral or trans-arterial access. These recesses can be connected via corresponding grooves to the distal or proximal-side end face of the cylindrical body.

**[0066]** The configuration and size of the recesses formed in the material of the cylindrical body are chosen so that a fastening or retaining element of a heart valve stent mounted in the catheter tip of complementary form to the recess can be accommodated, preferably by positive fit, in each of the recesses, so that each retaining element of the stent is in releasable engagement with a recess of the fixing device.

**[0067]** In this connection, it would be possible for the retaining elements of the stent to be formed at the second retaining region of the stent in the form of projecting elements, for example. These retaining elements of the stent, in the form of projecting elements in the example, can each be connected to the positioning hoops of the

stent by means of a neck section. When the retaining elements of the stent are mounted in the recesses of the stent holder, preferably by positive fit, at least the end regions of the neck sections are in the grooves that are formed in the material of the cylindrical body of the stent holder.

**[0068]** Irrespective of the particular embodiment of the stent holder, it is a basic requirement that the retaining elements of the stent holder (projecting elements and recesses) are covered during the insertion procedure and during the positioning of the stent at the implantation site, in common with the retaining elements located at the second retaining region of the stent, by the sleeve-shaped first housing portion of the catheter tip. This ensures that the engagement between the retaining elements of the stent and the retaining elements of the stent holder is secure and that the second retaining region of the stent is still held positively in its folded-up state.

**[0069]** In this position it is possible to check the function of the already unfolded heart valve prosthesis. Once a check has been made to ensure that the heart valve prosthesis is functioning correctly - by a further manipulation of the first housing portion (stent sheath) of the catheter tip with the first operating means - the region of the first housing portion previously covering the retaining elements of the stent holder at the distal part of the stent can be moved farther in the longitudinal direction of the catheter tip relative to the fixing mechanism of the catheter tip so the first housing portion no longer covers the respective retaining elements of the stent holder and the stent. As a result, the engagement between the retaining elements etc. provided at the distal end of the stent and the retaining elements of the stent holder can be released, which causes the distal part of the stent to be released as well and thus completely unfolded.

**[0070]** If, however, the check shows that the already partially implanted heart valve prosthesis is not able to fulfil its function or is not able to do so satisfactorily, the insertion system proposed by the invention has the particular advantage of retracting the stent with the heart valve prosthesis back into the catheter tip by moving the respective housing portions of the catheter tip appropriately in the opposite direction and of removing all parts of the insertion system, in other words the catheter tip with the catheter and the stent accommodated in the catheter tip, out of the body of the patient so that the risk of the operation is substantially reduced and a further attempt at implantation can be made on the same patient.

**[0071]** To ensure that, as far as possible, no damage can take place to the vessel wall during insertion of the catheter tip into the body of the patient when, for example, the catheter tip is inserted trans-arterially, and no injury can occur within the interior of the heart when, for example, the catheter tip is inserted trans-apically, it is preferable if the catheter tip in particular has a rotationally symmetrical form and preferably a rounded shape.

**[0072]** As the catheter tip is inserted, the catheter tip further should be completely closed, as far as possible,

and, to facilitate insertion through the aorta, should have a tip on the proximal end that is particularly preferably of a flexible material, for example silicone.

**[0073]** To simplify the actual introduction of the catheter system with the catheter tip provided at the proximal end of the catheter system into the body of the patient, a guide wire may also be provided which is guided through the complete catheter system. Such guide wires are already used in similar operations and are guided through the aorta of the patient to the heart before the catheter system is inserted. The catheter system, together with the catheter tip, can then be threaded over the guide wire and pushed along it into the aorta as far as the patient's heart.

**[0074]** The catheter system used with the insertion system proposed by the invention should also be advantageously configured so that a liquid coolant or drug can be circulated through the internal hollow catheter system as far as the catheter tip. With the aid of such a liquid coolant, for example in the form of a saline solution, a heart valve stent accommodated in the catheter tip can be appropriately cooled while the catheter tip is being advanced to the implantation site. This is of particular advantage when a shape memory material is used as the material of the heart valve stent, which is designed so that the stent deforms from a temporary shape to a permanent shape under the action of an external stimulus, whereby the temporary shape exists in a first configuration of the stent (in the folded-up state, when the stent is accommodated in the catheter tip of the insertion system) and the "permanent shape" in a second configuration of the stent (in the expanded state of the stent after release of the stent from the catheter tip).

**[0075]** It should be noted that the "permanent shape" of the expanded stent is totally adapted to the native shape of its surrounding area. This makes allowance for the fact that the native shape of the surrounding area at the implantation site differs from patient to patient. The property of the stent whereby the "permanent shape" of the expanded stent is automatically fully adapted to the surrounding environment consequently ensures that the heart valve prosthesis can always be implanted optimally.

**[0076]** An especially gentle implant procedure is possible when implanting the stent with the heart valve prosthesis mounted on it into the body of a patient with the insertion system of the invention, particularly if a shape memory material, for example Nitinol, i.e. an equi-atomic alloy of nickel and titanium, can be used for the stent.

**[0077]** If, as is preferable, the catheter system of the insertion systems proposed by the invention is designed so that a suitable coolant can be circulated through it, the stent mountable in the catheter tip can therefore be appropriately cooled while being advanced, to maintain the temperature of the stent material below the critical transition temperature. When the catheter tip with the cooled stent has been advanced to the implantation site, cooling of the stent is interrupted, at the latest when the

housing portions of the catheter tip are manipulated, as a result of which the stent is warmed to the body temperature (36°C) of the patient and the shape memory effect of the stent material is initiated.

5 **[0078]** Due to the self-expanding property of the individual components of the stent, radial forces are generated which act on the individual components of the stent, particularly the respective positioning hoops and retaining hoops, as well as the first and second retaining regions of the stent. Since the respective components of the stent remain in the respective housing portions of the catheter tip, the radial forces which build up and act on the individual components of the stent after the transition temperature has been exceeded are compensated by the respective housing portions of the catheter tip, so that  
10 - in spite of the initiation of the shape memory effect - the stent is retained positively in its first (folded-up) shape.

**[0079]** By an appropriate manipulation of the respective housing portions of the catheter tip, which is defined  
15 previously on the basis of the particular embodiment of the insertion system of the invention, the positioning hoops are then released from the catheter tip first - by a suitable stepwise release of the stent and the individual components of the stent from the respective housing portions of the catheter tip. Because of the action of the radial forces, the positioning hoops of the stent are opened in  
20 a radial direction. The opened stretched positioning hoops can then be positioned in the recesses/pockets of the native heart valve.

**[0080]** The remaining components of the stent are then released from the catheter tip. The released remaining components of the stent, in particular the retaining hoops with the heart valve prosthesis attached e.g. with the aid of a thread, then open in a radial direction and consequently the heart valve prosthesis attached to the retaining hoops unfolds like an umbrella.  
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**[0081]** The radial forces acting on the retaining hoops of the stent but also on the distal retaining region of the endoprosthesis result in the stent being pressed against the vessel wall in a radial direction. On the one hand, this results in secure anchoring of the stent with the opened heart valve prosthesis at the implantation site and, on the other hand, of reliably sealing the heart valve prosthesis in the second retaining region of the stent.  
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**[0082]** For flushing or rinsing the catheter system with coolant etc., it is particularly preferred that the handle has at least one syringe adapter for delivering and/or discharging a fluid to or from the catheter system.  
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**[0083]** To monitor the insertion procedure of the catheter system as well as the manipulation of the bendable region of the deflecting mechanism, which may optionally be provided on the proximal end of the catheter system, it is advantageous to provide marking elements on the catheter tip and/or at appropriate points of the catheter system, which are made from a material that absorbs X-ray radiation, for example, so that the respective position of the catheter tip and/or the catheter system can be detected on the X-ray image during the operation.  
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**[0084]** A screen filter may of course also be used with the insertion system of the invention, so that penetration of particles into the bloodstream of the respective patient can be prevented. Such a screen filter may be attached to the insertion system or the catheter system so that it extends completely around it radially. When used, it should be elastically biased so that it lies against the vessel wall in the aorta to thus ensure a particle-tight closure.

**[0085]** The insertion system proposed by the invention may additionally be provided with a conventional balloon, which can be disposed in the interior of the catheter system or the catheter tip and carried along with it or also passed through the interior of the catheter system to the expanding heart valve stent. With such a balloon, the volume of which can be which can be increased accordingly e.g. by a fluid under elevated pressure, the expansion of the anchoring support can be further assisted.

**[0086]** As explained above, the stent of the medical device, which can be inserted into the body of the patient with the aid of the insertion system described above, preferably has a one-piece structure cut integrally from a metal tube, in which a retaining hoop is associated with each positioning hoop and in which, at the distal end of the endoprosthesis, each end portion of the positioning hoop is connected to the end portion of the associated retaining hoop. Thus, on the one hand, it is possible to dispense with plastic hinges or similar connecting devices for the stent. On the other hand, the stent preferably used with the medical device proposed by this invention is an endoprosthesis which has a minimum longitudinal extension and offers a positioning function by means of the positioning hoops on the one hand and the function of retaining a heart valve prosthesis by means of retaining hoops on the other hand.

**[0087]** It is clear that, during the transition of the stent form the first pre-definable mode to the second pre-definable mode due to a widening in the cross-section of the entire stent, the retaining hoops on the one hand and the positioning hoops on the other hand are opened in a radial direction. This being the case, the second mode of the stent is advantageously selected so that as the retaining and positioning hoops are being opened, they abut against the vessel wall of the aorta and form a positive connection with it, thereby firmly anchoring the stent and the heart valve prosthesis at the implantation site.

**[0088]** Due to the fact that the structure of the stent results in a particularly short design of the catheter tip of the insertion system, the catheter tip of the insertion system can be manoeuvred in the patient's body particularly easily, which is of particular advantage if the implantation route to the heart valve to be replaced is via the aortic arch. The minimal length of the catheter tip of the insertion system is ensured particularly by the special structure of the stent.

**[0089]** Accordingly, using the insertion system proposed by the invention, the positioning and retaining hoops of such an anchoring stent at the implantation site

can be disposed and dimensioned with a view to automatically initiating a sequential self-expansion of the stent with the heart valve prosthesis. For this to take place, it is preferably provided that the stent together with the heart valve prosthesis fastened to it, where required, are mounted for the purpose of implantation in the interior of the catheter tip that forms part of the insertion system. This catheter tip is guided via the catheter system of the insertion system through the aorta of the patient, for example, or from the apex of the heart, to the implantation site (to the diseased heart). On reaching the implantation site, the catheter tip of the insertion system is manipulated so that the positioning hoops can be released to permit their self-expansion. Subsequently the catheter tip of the insertion system with the already partially expanded stent is moved and aligned so that the positioning hoops are inserted into the pockets of the native heart valve. This allows the stent to be precisely positioned in relation to the native heart valve.

**[0090]** The catheter tip of the insertion system is further manipulated so that the retaining hoops of the anchoring stent are also released, as a result of which they automatically expand. As this happens, the heart valve flaps of the native heart valve are clamped between respective positioning and retaining hoops and the heart valve prosthesis attached to the proximal retaining region of the anchoring stent is opened.

**[0091]** Once the anchoring stent incorporating the heart valve prosthesis has been implanted, the catheter system with the catheter tip is withdrawn from the body of the patient.

**[0092]** Naturally, due to the increased control afforded by the implantation system it is also conceivable, for example, for a heart valve stent to be implanted in a two-part procedure, carried out either during separate procedures or as separate parts of the same procedure. In a first part, for example, an anchoring stent is introduced to an implantation site. In a second part, a secondary stent with a valve prosthesis is introduced to the implantation site. The secondary stent comprises appropriate functional components that can co-operate and engage with the anchoring stent. Thus, the secondary stent accommodates and retains a heart valve prosthesis on the one hand, whilst co-operating with the anchoring stent to anchor and retain the heart valve stent with the valve prosthesis in position on the other.

**[0093]** Since the implantation system both increases control and enhances the ability to accurately position an implant such as a stent, it would also be conceivable to replace a failing valve from a previously implanted heart valve with a new valve prosthesis. The functional components position and secure the new, or secondary, heart valve stent at the implantation site of the previously implanted heart valve stent and accommodate and retain the new, or secondary, heart valve prosthesis. Thus, by way of example, a new heart valve stent with valve prosthesis could be implanted within a previously implanted heart valve stent in the same manner as implantation of

a first heart valve stent with prosthesis. Preferred embodiments of the solution proposed by the invention will be described with reference to the appended drawings below.

**[0094]** Of these:

Fig. 1: an embodiment of an insertion system for trans-apical insertion of a self-expandable heart valve stent in a side elevation;

Fig. 2: a part-sectioned side elevation of the trans-apical insertion system in accordance with Fig. 1;

Fig. 3a-d: side elevations of the trans-apical insertion system in accordance with Fig. 1 in its four previously defined functional states to clarify the loading procedure of the insertion system;

Fig. 4a-d: side elevations of the trans-apical insertion system in accordance with Fig. 1 in its four previously defined functional states to clarify the release procedure of a stent housed in the catheter tip of the insertion system;

Fig. 5: an embodiment of a handle for an insertion system for trans-apical insertion of a self-expandable heart valve stent in a side elevation;

Fig. 6: a further embodiment of a handle for an insertion system for transapical insertion of a self-expandable heart valve stent in a side sectional elevation;

Fig. 7: a plan view of a handle in accordance with Fig. 6;

Fig. 8: an embodiment of a catheter tip for an insertion system for transapical insertion of a self-expandable heart valve stent in a side sectional elevation;

Fig. 9: an embodiment of a catheter system for an insertion system for trans-apical insertion of a self-expandable heart valve stent in a cross-sectional elevation;

Fig. 10a-d: three-dimensional side elevation of an embodiment of a catheter tip for a trans-apical insertion system in different functional states to illustrate a trans-apical implantation procedure of a heart valve stent;

Fig. 11a: an embodiment of an insertion system for

trans-femoral / trans-arterial insertion of a heart valve stent in a side elevation;

Fig. 11b: a side elevation of the trans-femoral / trans-arterial insertion system in accordance with Fig. 11a with a deflected catheter system;

Fig. 12: a further embodiment of an insertion system for trans-femoral / trans-arterial insertion of a heart valve stent in a side elevation;

Fig. 13: a further embodiment of an insertion system for trans-femoral / trans-arterial insertion of a heart valve stent in a side elevation;

Fig. 14a-d: side elevations of the trans-femoral / trans-arterial insertion system in accordance with Fig. 11a in its four previously defined functional states to illustrate the loading procedure of the insertion system

Fig. 15a-d: side elevations of the trans-femoral / trans-arterial insertion system in accordance with Fig. 11a in its four previously defined functional states to illustrate the release procedure of a stent housed in the catheter tip of the insertion system;

Fig. 16: a further embodiment of an insertion system for trans-femoral / trans-arterial insertion of a self-expandable heart valve stent in a part-sectioned side elevation;

Fig. 17: an embodiment of a handle for an insertion system for trans-femoral / trans-arterial insertion of a self-expandable heart valve stent in a part-sectioned side elevation;

Fig. 18: an embodiment of a catheter tip for an insertion system for trans-femoral / trans-arterial insertion of a self-expandable heart valve stent in a part-sectioned side elevation;

Fig. 19: an embodiment of a catheter system for an insertion system for trans-femoral / trans-arterial insertion of a self-expandable heart valve stent in a cross-sectional elevation;

Fig. 20: a schematic view to illustrate a trans-femoral / trans-arterial implantation procedure of a heart valve stent; and

Fig. 21a-c: three-dimensional schematic part-sec-

tioned view on the catheter tip of a trans-femoral / trans-apical insertion system in different functional states to illustrate the implantation procedure of a heart valve stent mounted in the catheter tip.

**[0095]** An embodiment of an insertion system 100-1 for trans-apical insertion of a self-expandable cardiac valve stent into the body of a patient is described in the following with reference to Figures 1 to 4. Figures 3a-d and Figures 4a-d show the insertion system 100-1 of this embodiment in its four different previously definable functional states, while Figures 1 and 2 show the insertion system 100-1 in a side elevation and partly sectioned side elevation.

**[0096]** The insertion system 100-1 shown in Figures 1 to 4 is suitable for a trans-apical access to a heart valve requiring treatment, for example an aortic valve. With the insertion system 100-1, it is possible to implant a self-expandable heart valve stent trans-apically, thus approaching from the apex of the heart, in the body of a patient. To this end, the insertion system 100-1 has a catheter system 30-1, by means of which the heart valve stent not shown explicitly in Figures 1 to 4 can be introduced in its folded-up state into the body of the patient.

**[0097]** In the insertion system 100-1 according to Figures 1 to 4, a catheter tip 10-1 is provided at the proximal end region of the catheter system 30-1, in which the heart valve stent to be implanted into the body of the patient can be housed. At the distal end region of the catheter system 30-1, a handle 70-1 is provided, with which the catheter tip 10-1 can be manipulated.

**[0098]** In detail, the catheter tip 10-1 of the trans-apical insertion system has a stent holder 15 by means of which the second retaining region of the stent to be implanted into the body of the patient with the catheter tip 10-1 can be releasably fixed. Further, the catheter tip 10-1 comprises a housing portion for accommodating at least the first retaining region of the stent. In detail, the housing portion consists of a first housing portion 11 and a second housing portion 21.

**[0099]** In the insertion system 100-1 designed for trans-apical access, it is provided that the first housing portion 11 of the catheter tip 10-1 is in the form of a stent sheath, which is connected to the proximal end of tip 25 of the catheter tip 10-1, with its opening pointing in the direction of the distal end region of the catheter tip 10-1. The first housing portion 11, in the form of a stent sheath, forms the outer circumferential surface of the catheter tip 10-1 when this - as shown, for example, in Fig. 4a - is in its closed state.

**[0100]** In the insertion system 100-1 designed for a trans-apical access, the second housing portion 21 of the catheter tip 10-1 is in the form of a stent funnel, whose opening points in the direction of the proximal end tip 25 of the catheter tip 10-1. The retaining hoops of the stent and the heart valve prosthesis, where required, fastened to the retaining hoops, can be mounted in the interior of

the second housing portion 21 in the form of the stent funnel. The second housing portion 21 in the form of the stent funnel can be telescopically accommodated by the first housing portion 11 in the form of the stent sheath, when the catheter tip 10-1 (see Fig. 4a) is in the closed state. In this way, the positioning hoops of the stent are located between the outer circumferential surface of the stent funnel and the inner circumferential surface of the stent sheath when a heart valve stent is mounted in the catheter tip 10-1.

**[0101]** In relation to the handle 70-1 of the trans-apical insertion system 100-1, it is provided that this has a first operating means 71 associated with the first housing portion 11 and a second operating means 81 associated with the second housing portion 21. The first operating means 71 cooperates with the first housing portion 11 of the catheter tip 10-1 so that, on actuation of the first operating means 71, a previously definable longitudinal displacement of the first housing portion 11 can be effected relative to the stent holder 15. In addition, the second housing portion 81 of the handle 30-1 cooperates with the second housing portion 21 of the catheter tip 10-1 so that, on actuation of the second operating means 81, a previously definable longitudinal displacement of the second housing portion 21 of the catheter tip 10-1 can be effected relative to the stent holder 15.

**[0102]** With the insertion system 100-1 designed for trans-apical access, on actuation of the first operating means 71 of the handle 70-1, the first housing portion 11 of the catheter tip 10-1 can be moved in the longitudinal direction L of the catheter tip 10-1 relative to the stent holder 15, whereby the movement of the first housing portion 11 takes place in a proximal direction, thus away from the handle, to open the catheter tip 10-1 or to release a stent mounted in the catheter tip 10-1 (see Figs. 4b und 4d).

**[0103]** With the insertion system designed for trans-apical access, on actuation of the second operating means 81 of the handle 70-1, the second housing portion 21 of the catheter tip 10-1 can likewise be moved in the longitudinal direction L of the catheter tip 10-1 relative to the stent holder 15. In particular, the second housing portion 21 is moved in the direction of the proximal end tip 25 of the catheter tip 10-1 to release a stent mounted in the catheter tip 10-1 (see Fig. 4c).

**[0104]** In relation to the stent holder 15 forming part of the catheter tip 10-1, it is provided in the embodiment of the trans-apical insertion system 100-1 shown in Figures 1 to 4 that the stent holder 15 is in the form of a crown with a total of three projecting elements 16. The projecting elements 16 of the crown are complementary to retaining elements, for example implemented as retaining rings, which are implemented on a retaining region of a stent mounted or mountable in the catheter tip 10-1. Thus it is possible for the projecting elements 16 of the crown to form a releasable engagement with the retaining elements of the stent, therefore, in order to fasten the stent releasably to the stent holder 15 of the catheter tip 10.

**[0105]** As already explained, with the trans-apical insertion system 100-1 it is provided that the first housing portion 11 of the catheter tip 10-1 is designed as a tubular or sleeve-shaped element, which acts as stent sheath and which is connected permanently to the end tip 25 of the catheter tip 10-1. The proximal-side end tip 25 of the catheter tip 10-1 is formed from the most inelastic material possible, such as a relatively strong plastic material or metal. A bonded and/or positive locking connection is particularly suitable for the joint between the end tip 25 and the first housing portion 11 in the form of the stent sheath.

**[0106]** On the other hand, the proximal-side end tip 25 of the catheter tip 10-1 is connected to the first operating means 71 of the handle 70-1 by means of a first force transmission means 31 in the form of an inner catheter. This has the result that, on actuation of the first operating means 71, the proximal-side end tip 25 of the catheter tip 10-1 can be displaced together with the first housing portion 11 permanently attached to it relative to the stent holder 15 in the longitudinal direction L of the catheter tip 10-1.

**[0107]** As can be seen particularly in the illustration in Fig. 2, in the trans-apical insertion system 100-1 an inner catheter in the form of a cannula tube acts as first force transmission means 31, which allows the transmission of tensile and shear forces from the first operating means 71 of the handle 70-1 to the proximal-side end tip 25 and consequently to the first housing portion 11 of the catheter tip 10-1. In detail, the inner catheter in the form of a cannula tube (first force transmission means 31) extends from a first injection adapter 99a provided at the distal end of the handle 70-1 in the direction of the longitudinal axis L of the insertion system 100-1 to the proximal-side end tip 25 and is used to receive and guide a guide wire not explicitly shown in Figures 1 to 4, as well as for draining and supplying fluid from or to the catheter tip 10-1, as can be necessary where applicable during insertion of the catheter tip 10-1 into the body of the patient.

**[0108]** In the trans-apical insertion system 100-1, the second housing portion 21 of the catheter tip 10-1 is in the form of a stent funnel configured as a tubular or sleeve-shaped element. The stent funnel (second housing portion 21) is connected by means of a second force transmission means 41 to the second operating means 81 of the handle 70-1 so that, on actuation of the second operating means 81, tensile or shear forces can be transmitted to the second housing portion 21 of the catheter tip 10-1. This allows the second housing portion 21 in the form of a stent funnel to be displaced relative to the stent holder 15 on one side and the first housing portion 11 on the other side in the longitudinal direction L of the catheter tip 10-1.

**[0109]** As already indicated, with the trans-apical insertion system 100-1, it is preferred that the first housing portion 11 of the catheter tip 10-1 is in the form of a stent sheath, for example a long extended capillary. The second housing portion 21 is preferably implemented as a

stent funnel, also in the form of a long extended capillary, for example. The inside diameter of the tubular or sleeve-shaped first housing portion 11 should be chosen to be larger than the outside diameter of the similarly tubular or sleeve-shaped second housing portion 21, so that the second housing portion 21 can be accommodated telescopically inside the first housing portion 11.

**[0110]** In the embodiment of the trans-apical insertion system 100-1 shown in Figures 1 to 4, the stent holder 15 is in the form of a cylindrical element, which is equipped with suitable retaining elements 16. The retaining elements 16 are used to form a releasable connection with a retaining region of a heart valve stent not shown in the representations in Figs. 1 to 4, when this heart valve stent is mounted in the catheter tip 10-1. It is also possible to configure the retaining elements 16 of the stent holder 15 so that these can form a releasable engagement with the retaining elements of the stent.

**[0111]** In the representations in Figs. 1 to 4, the retaining elements 16 on the stent holder 15 are designed as projecting elements which can be brought into engagement with corresponding retaining rings of complementary form. However, it would also be possible to form the retaining elements 16 of the stent holder 15 as depressions or recesses which are introduced into the cylindrical body of the stent holder 15 and which are designed to accommodate corresponding retaining elements of complementary form of the heart valve stent.

**[0112]** In the trans-apical insertion system 100-1 in accordance with the embodiment shown in Figs. 1 to 4, the stent holder 15 is permanently located relative to the handle 70-1 so that, for example, when the handle 70-1 is rotated about the longitudinal axis L of the insertion system 100-1, the stent holder 15 participates in this rotary movement. It is possible here for the stent holder 15 to be connected with the handle 70-1 by means of a connecting means permanently attached to the body 70' of the handle 70-1.

**[0113]** More detail is given in the following of an embodiment of a catheter system 30-1 for a trans-apical insertion system 100-1 with reference to Figures 2, 6, 8 and 9.

**[0114]** The catheter system 30-1 is used to introduce an expandable heart valve stent in its folded-up state into the body of the patient. At the proximal end region 39 of the catheter system 30-1 is the catheter tip 10-1, in which the heart valve stent is or can be accommodated with the aid of the first and second manipulable housing portion 11, 21. At the distal end region 49 of the catheter system 30-1 is a handle 70-1, yet to be described in more detail, which is used for appropriate manipulation of the manipulable housing portions 11, 21 of the catheter tip 10-1, to allow a stepwise release of the heart valve stent from the catheter tip 10-1.

**[0115]** In detail, the catheter system 30-1 exhibits at least one first force transmission means 31 and at least one second force transmission means 41, whereby the first force transmission means 71 of the handle 70-1 con-

nects to the first housing portion 11 of the catheter tip 10-1. The second operating means 81 of the handle 70-1 is connected by means of the second force transmission means 41 with the second housing portion 21 of the catheter tip 10-1.

**[0116]** In the embodiment of the catheter system 30-1 shown in Figures 2, 6, 8 and 9, the second force transmission means 41 is configured as a tubular element, the distal end of which is connected to the second operating means 81 of a handle 70-1. The proximal end of the second force transmission means 41 in the form of an outer catheter merges into the second housing portion 21 of the catheter tip 10-1 in the form of the stent funnel in a region between the catheter system 30-1 and the catheter tip 10-1. It is possible to configure the second housing portion 21 in the form of the stent funnel and the second force transmission means 41 in the form of the outer catheter in one piece. However, there is also of course the possibility of joining the distal end of the second housing portion 21 in the form of the stent funnel to the proximal end of the second force transmission means 41 in the form of the outer catheter, for example by bonding them using an adhesive.

**[0117]** So that there is no step or edge in the transition region between the catheter system 30-1 in the catheter tip 10-1 which can lead to an injury to the tissue of the apex of the heart during the insertion of the catheter system 30-1 (i.e. with the catheter tip 10-1 in the closed state), it is preferable that the outside diameter of the second force transmission means 41 in the form of the outer catheter is essentially identical to the outside diameter of the first housing portion 11 in the form of the stent sheath. This can be achieved by providing at least one step between the second housing portion 21 in the form of the stent funnel and the second force transmission means 41 in the form of the outer catheter.

**[0118]** In the embodiment of the catheter system 30-1 shown in Figures 2, 6, 8 and 9 for the trans-apical insertion system 100-1, a catheter in the form of a cannula tube is used as first force transmission means 31, extending in the implementation, for example according to the illustrations in Figures 1 to 4, from the distal end region of the handle 70-1 to the proximal-side end tip 25 of the catheter tip 10-1.

**[0119]** The first force transmission means 31 implemented as a cannula tube can be connected at the distal end of the insertion system 100-1 to a (first) injection adapter 99a; it would be possible, for example, to form the distal end of the first force transmission means 31 as the injection adapter 99a.

**[0120]** When the insertion system 100-1 is used for implanting an expandable heart valve stent accommodated in the catheter tip 10-1 at the implantation location in the heart, it is preferable that a guide wire (not explicitly shown in the drawings) is passed through the first force transmission means 31 implemented as a cannula capillary.

**[0121]** As already indicated, it is provided with the

trans-apical insertion system 100-1 that the stent to hold 15 of the catheter tip 10-1 is preferably permanently attached to the handle 70-1 or the body 70' of the handle 70-1 so that, in relation to the stent holder 15, in particular the degree of freedom of rotational movement about the longitudinal axis L of the insertion system 100-1 and a degree of freedom of movement in the direction of the longitudinal axis L of the insertion system 100-1 are frozen. Thus the stent holder 15 cannot be moved at least in the longitudinal direction L of the insertion system 100-1 relative to the body 70' of the handle 70-1. Likewise, a rotational movement of the stent holder 15 about the longitudinal axis L of the handle 70-1 is excluded.

**[0122]** The stent holder 15 is fixed relative to the handle 70-1, for example, by means of a connecting means 42 permanently attached to the body 70' of the handle.

**[0123]** In a preferred implementation of the catheter system 30-1 used with the trans-apical insertion system 100-1, it is provided that the second force transmission means 41, which connects the second operating means 82 of the handle 70-1 to the second housing portion 21 in the form of the stent funnel, is implemented as an outer catheter, while the first force transmission means 41 implemented as a cannula capillary is passed through the interior of the outer catheter (second force transmission means 41). A further cannula capillary, for example, can be considered as connecting means 42 to fix the stent holder 15 relative to the handle 70-1, running through the interior of the second force transmission means 41 in the form of the outer catheter. The first force transmission means 31 implemented as a cannula capillary is then passed through the interior of the connecting means 42 in the form of a cannula capillary. Alternatively, as connecting means, it is possible to use a further cannula capillary which runs both through the outer catheter capillary and through the first force transmission means 41 implemented as cannula capillary.

**[0124]** Thus the first housing portion 11 of the catheter tip 10-1 of the trans-apical insertion system 100-1 is designed to accommodate the second housing portion 21 of the catheter tip 10-1 with the functional components of the stent mounted in it, for example with retaining hoops of the stent.

**[0125]** In relation to the embodiment of a handle 70-1 for the trans-apical insertion system 100-1 in accordance with Figures 1 to 7, it is preferably provided that the first operating means 71, which cooperates with the first housing portion 11 of the catheter tip 10 by means of the first force transmission means 31, has a first slide 74 guided in a first guide 72 and functionally connected to a first pusher 73. This first slide 74 cooperates with the first housing portion 11 of the catheter tip 10-1 associated with the first operating means 71 by means of the first force transmission means 31 so that, on actuation of the first operating means 71, tensile and shear forces can be transmitted from the first slide to the first housing portion 11 (stent sheath) of the catheter tip 10-1.

**[0126]** With the handle 70-1 for the trans-apical inser-

tion system 100-1, a second operating means 81 is further provided, which is functionally connected by means of the second force transmission means 41 to the second housing portion 21 of the catheter tip 10-1. The second actuating means 81 has a second slide 84 guided in a second guide 82 and functionally connected to a second pusher 83, whereby this second slide 84 is functionally connected with the second housing portion 21 of the catheter tip 10-1 associated with the second operating means 81 by means of the second force transmission means 41 so that, on actuation of the second operating means 81 and, in particular, on actuation of the second slide 84, force can be directly transmitted from the second slide 84 to the second housing portion 21 (stent funnel) of the catheter tip 10.

**[0127]** In relation to the second actuating means 81 of the handle 70-1 used with the insertion system 100-1 shown in Figures 1 to 4, it is further provided that the handle 70-1 has a first and a second stop 85, 86, each associated with the second operating means 81 and designed to define the longitudinal displacement stroke of the second housing portion 21 (stent funnel) of the catheter tip 10-1 that can be effected by actuation of the second operating means 81. In particular, the displacement distance (displacement stroke) that can be realised with the second pusher 83 of the second operating means 81 is correspondingly defined.

**[0128]** It is further provided with the trans-apical insertion system 100-1 in accordance with the first embodiment that the handle 70-1 has a first and a second stop 75, 76, which are each associated with the first operating means 71 and which define the overall longitudinal displacement stroke of the first housing portion 11 (stent sheath) of the catheter tip 10-1 that can be effected on actuation of the first operating means 71.

**[0129]** In addition to the first and second stops 75, 76 associated with the first operating means 71, the handle 70-1 in the embodiment of the trans-apical insertion system 100-1 shown in Figures 1 to 4 comprises a further, third stop 77 associated with the first operating means 71, which cooperates with the first stop 75 on one side and the second stop 76 on the other so that, on actuation of the first operating means 71, a stepwise longitudinal displacement of the first slide 74 on the first guide 72 can be effected, consisting of two separate steps, and consequently a stepwise longitudinal displacement, consisting of two separate steps, of the first housing portion (stent sheath) of the catheter tip 10-1 relative to the stent holder 15 and crown of the catheter tip 10-1.

**[0130]** While the third stop 77 associated with the first operating means 71 is suitably positioned on the first guide 72 between the first and second stop 75, 76 associated with the first operating element 71, the first and third stop 75, 76 on one side and the second and third stop 76, 77 on the other define the longitudinal displacement stroke of the first housing portion 11 (stent sheath) of the catheter tip 10-1 on each separate step that is effected on actuation of the first operating means 71.

**[0131]** In the embodiment of the trans-apical insertion system 100-1 shown in Figures 1 to 4, it is provided that the third stop of the handle 70-1, specified previously, which is associated with the first operating means 71, is in the form of a stop element 77' releasably fastened on the first guide 72 of the first slide 74.

**[0132]** Finally, it is further provided for the handle 70-1 of the trans-apical insertion system 100-1 shown in Figures 1-4 that the first operating means 71 and the second operating means 81 are each associated with at least one securing element 79, 89. In particular, the first securing element 79 associated with the first operating means 71 of the handle 70-1 is implemented as an element that can be removed from the first slide 74 or from the first pusher 72 of the first operating means 71. This securing element 79 cooperates with the first slide 74 so that the longitudinal displacement of the first housing portion 11 (stent sheath) of the catheter tip 10-1 that can be effected with the first operating means 71 can be blocked.

**[0133]** The second securing element 89, which is associated with this second operating means 84, is similarly implemented as an element that can be removed from the second slide 84 or from the second pusher 83 of the second operating means 81 which cooperates with the second operating means 81 so that a longitudinal displacement of the second housing portion 21 (stent funnel) of the catheter tip 10-1 that can be effected with the second operating means 80 can be blocked.

**[0134]** The four different functional states realisable with a trans-apical insertion system 100-1 are described in the following, initially with reference to the drawings in Figures 4a to 4d.

**[0135]** Fig. 4a shows an embodiment of a trans-apical insertion system 100-1 in its first functional state, in which the catheter tip 10-1 is completely closed. As already indicated, a self-expandable heart valve stent (not shown in Fig. 4a) can be housed in the catheter tip 10-1 in the corresponding housing portion 11, 12 of the catheter tip 10-1.

**[0136]** In the first functional state in accordance with Fig. 4a, the respective pushers 73 and 83 and the respective slides 74 and 84 of the operating means 71 and 81 are located in their first position (Pos. 1). In particular, the second pusher 83 of the second operating means 81 abuts the first stop 85 provided on the catheter tip-side end of the second guide 82. In this first position, the second pusher 83 is fixed by the securing element 83 so that a longitudinal displacement of the second pusher 83 and the slide 84 of the second operating means 21 on the second guide 82 in the direction of the second stop 86 associated with the second operating means 21 is blocked.

**[0137]** In the first functional state in accordance with Fig. 4a, the first pusher 73 and the first slide 74 of the first operating means 71 are also in the first position (Pos. 1) at the first stop 75 of the first operating means 71. The first stop 75 of the first operating means 71 is located at the distal end of the first guide 72. In this first position,

the first pusher 74 and the first slide 74 of the first operating means 71 is anchored with the aid of the second securing element 89, to block a longitudinal displacement of the first pusher 73 and the first slide 74 along the first guide 72 in the direction of the catheter tip 10.

**[0138]** As already indicated, the catheter tip 10-1 of the insertion system 100-1 is in a completely closed state in the first functional state of the trans-apical insertion system 100-1 (see Fig. 4a). In this state, the first and second housing portion 11, 12 of the catheter tip 10-1, in the form of sleeve-shaped elements interlock telescopically. The respective inside and outside diameters of these sleeve-shaped elements are appropriately coordinated with one another. As is described in detail in the following, the sleeve-like first and second housing portion 11, 21 of the catheter tip 10-1 are coordinated with one another in relation to their respective inside and outside diameters so that the folded-up retaining hoops of the stent mounted or to be mounted in the catheter tip 10 with the heart valve prosthesis fastened to them can be held in the second housing portion 21 in the form of the stent funnel. The folded-up positioning hoops of the stent are housed between the second housing portion 21 in the form of the stent funnel and the first housing portion 11 in the form of the stent sheath and are held in their folded form.

**[0139]** The catheter tip 10-1 can be inserted into the body of the patient in the first functional state of the insertion system 100-1 (see Fig. 4a) and can be advanced to the desired implantation location. With the trans-apical insertion system 100-1 in accordance with the first embodiment, access to the implantation location, i.e. to the diseased heart, can be carried out trans-apically, thus approaching from the apex of the heart, since the stent holder 15 is located at the proximal region of the catheter tip 10-1, while distal from this is the second housing portion 21 (stent funnel) of the catheter tip 10-1.

**[0140]** Fig. 4b shows the insertion system 100-1 in accordance with Fig. 4a in its second functional state. This second functional state is discontinued as soon as the catheter tip 10-1 has reached the implantation location in the body of the patient. As is explained in detail in the following, with reference to Figures 4b to 4d, when the catheter tip 10-1 has reached the implantation location, the appropriate manipulations of the individual housing portion 11, 21 of the catheter tip 10-1 are carried out. These manipulations are necessary to release the stent housed in the catheter tip 10-1 in the steps in accordance with a previously defined sequence of events. How this stepwise release of the stent mountable or mounted in the catheter tip 10 can be implemented with the aid of the insertion system 100-1 through directed movements of the individual housing portion 21, 11 of the catheter tip 10-1 is described in detail in the following.

**[0141]** After the catheter tip 10-1 has reached the implantation location, the insertion system 100-1 is transferred from the first functional state shown in Fig. 4a to the second functional state shown in Fig. 4b by actuation of the first operating means 71. In particular, the securing

element 79 associated with the first operating means 71 is removed, as a result of which blocking of the capacity of the first pusher 73 and the first slide 74 for longitudinal displacement is removed.

**[0142]** After removal of the securing element 79 from the first operating means 71 and after the removal of the block on the first pusher 73 and the first slide 74, the first pusher 73 and the first slide 74 are moved along the first guide 72 in the direction of the catheter tip 10-1 from the first position (Pos. 1) to the second position (Pos. 2). The second position (Pos. 2) is determined by the third stop 77 located between the first stop 75 (Pos. 1) and the second stop 76.

**[0143]** The first housing portion 11 (stent sheath) of the catheter tip 10-1 associated with the first operating means 71 is moved by an actuation of this type of the first operating means 71 in a proximal direction relative to the stent holder 15. The amount of movement, i.e. the degree of longitudinal displacement of the first housing portion 11 (stent sheath) of the catheter tip 10-1 relative to the stent holder 15, is determined by the longitudinal displacement stroke between the first position (Pos. 1) and the second position (Pos. 2) that can be effected with the first pusher 73 and the first slide 74.

**[0144]** The resulting movement of the first mounting area 11 (stent sheath) of the catheter tip 10-1 relative to the stent holder 15 has the result that the telescopic-like overlapping between the two sleeve-shaped first and second housing portion 11, 21 is removed. For this purpose, the amount of movement of the first housing portion 11 relative to the stent holder 15 and relative to the second housing portion 21 and, consequently, the longitudinal displacement stroke that can be effected with the first pusher 73 and the first slide 74 is chosen so that the sleeve-shaped first housing portion 11 (stent sheath) no longer surrounds the second housing portion (stent funnel) telescopically but nevertheless covers the stent holder 15 and particularly the fixing elements 16 of the stent holder. As a result, in this second functional state of the insertion system 100-1 (see Fig. 4b), the heart valve stent mounted or mountable in the catheter tip 10-1 is kept anchored to the stent holder 15 of the catheter tip 10-1.

**[0145]** As is described in detail in the following with reference to the drawings of Figures 10a to 10d, in the second functional state of the insertion system 100-1 (see Fig. 4b) the retaining hoops 153 of a stent 150 mounted in the catheter tip 10-1 with a heart valve prosthesis fastened to them are held by the second housing portion 21 (stent funnel) of the catheter tip 10-1, still in their folded-up form, since these components of the stent 153 are accommodated unchanged from the first functional state in accordance with Fig. 4a in their folded-up form in the second housing portion 21 (stent funnel) of the catheter tip 10-1.

**[0146]** Likewise, the engagement between the retaining elements 151 provided on the stent 150 and the corresponding retaining elements 16 of the stent holder 15 in a complementary configuration is secured by means

of the distal end of the first housing portion 11, so that the second retaining region of the stent 150, on which its retaining elements 151 are provided, is also (still) in its folded-up state with the aid of the first housing portion 11. As already explained, this is made possible since the distal end of the first housing portion 11 still covers the stent holder 15 with the retaining elements 16.

**[0147]** On the other hand, however, the first housing portion 11 (stent sheath) of the catheter tip 10-1 has been moved by manipulation of the first operating means 71 away from the handle 70 in the proximal direction relative to the stent holder 15 and the second housing portion 21 (stent funnel), so that the positioning hoops 154 of the stent 150 mounted or mountable in the catheter tip are no longer covered by the first housing portion 11 (stent sheath). Expressed in another way, this means that, by the longitudinal displacement of the first housing portion 11 (stent sheath) effected in the second functional state of the insertion system 100-1, the telescopic-like housing of the positioning hoops 154 of the stent 150 between the first and second housing portion 11, 21 of the catheter tip 10-1 in the first functional state (see Fig. 4a) is ended. Thus in the second functional state of the insertion system 100-1 (see Fig. 4b) the first housing portion 11 (stent sheath) no longer undertakes the function of retaining the positioning hoops 154 of the stent 150 in their folded-up form, so that these are released and correspondingly can unfold.

**[0148]** As can be seen in detail in the illustrations in Figures 10a to 10d, the positioning hoops 154 of the stent 150 are opened after having been released because of the radial forces acting in a radial direction. These opened positioning hoops 154 can be positioned in the pockets of the native heart valve.

**[0149]** After the positioning hoops 154 of the stent 150 have been positioned in the pockets of the native heart valve, the insertion system 100-1 is transferred from the second functional state shown in Fig. 4b to the third functional state shown in Fig. 4c. This is done by removing the securing element 89 associated with the second operating means 81 of the handle 70-1 and consequently the longitudinal displaceability of the second push 83 and the second slide 84 is restored.

**[0150]** After the securing element 89 has been removed, the second pusher 83 and the second slide 84 are displaced along the second guide 82 from the first position (Pos. 1) to the second position (Pos. 2). The longitudinal displacement stroke that can be effected is defined by the second stop 86 of the second operating means 81, which is located at the distal end of the second guide 82.

**[0151]** As a result of the manipulation of the second operating means 21, the second housing portion 21 (stent funnel) of the catheter tip 10-1 associated with the second operating means 21 is moved relative to the stent holder 15 of the catheter tip 10-1 and also relative to the first housing portion 11 (stent sheath) in the distal direction towards the handle 70. The movement stroke of the

second housing portion 21 thus corresponds to the longitudinal displacement stroke effected between the second pusher 83 and the second slide 84. This movement of the second housing portion 21 (stent funnel) relative to the stent holder 15, on the one hand, and the first housing portion 11 on the other - by a suitable choice of the longitudinal displacement stroke that can be realised with the second operating means 81 - has the result that the second housing portion 21 no longer covers the first retaining region of the stent 150 with the retaining elements 151 and consequently the retaining hoops 153 of the stent 150 with the heart valve prosthesis fastened to them are released. Due to the radial forces acting on the retaining region, release of the retaining elements 151 of the stent 150 leads to a complete unfolding of the retaining region of the stent 150 (see Fig. 10d).

**[0152]** Since the distal end of the first housing portion 11 (stent sheath) of the catheter tip 10-1 still covers the stent holder 15 in the third functional state of the insertion system 100-1 (see Fig. 4c or Fig. 10c), though, the engagement between the retaining elements 16 of the stent holder 15 and the retaining elements 151 of the stent 150 remains secure, so that the stent 150, in spite of the unfolding of its retaining hoops 153, remains functionally connected to the catheter tip 10-1 of the insertion system 100-1 and an explantation of the stent 150 with the heart valve prosthesis attached to it is still possible. They explantation would take place according to a corresponding reverse sequence, whereby the first the insertion system 100-1 is transferred from the third functional state to the second functional state and then into the first functional state.

**[0153]** After the complete release of the retaining hoops 153 of the stent 150 and after a check of the function of the unfolded heart valve prosthesis, if there are no abnormalities during the check, the stent 150 is fully released. This is done by transferring the insertion system 100-1 from its third functional state shown in Fig. 4c to the fourth functional state shown in Fig. 4d.

**[0154]** In the fourth functional state, the stop element 77' provided between the first stop 75 and the second stop 76 on the first guide 72 of the first operating means 71, which defines the third stop 77 in the second functional state in accordance with Fig. 4b, has been removed. As a consequence, the first pusher 73 and the first slide 74 of the first operating means 71 can be moved further in the direction of the catheter tip 10-1 on the first guide 72 from the second position (Pos. 2) to the third position (Pos. 3). This third position (Pos. 3) is defined by the second stop 7b at the proximal end of the first guide 72. Thus a previously defined (further) displacement of the first slide 74 takes place, as a result of which the first housing portion 21 (stent sheath) associated with the first operating means 71 is moved by the longitudinal displacement stroke effected with the further manipulation of the first operating means 71 relative to the stent holder 15 in the proximal direction further away from the handle 70-1.

**[0155]** The longitudinal displacement stroke effected with the further manipulation of the first operating means 71 is chosen appropriately so that, with the movement of the first housing portion 11 (stent sheath) relative to the stent holder 15, cover of at least the retaining elements 16 of the stent holder 15 with the distal end region of the first housing portion 11 is eliminated. Removal of the cover of the retaining elements 16 of the stent holder 15 with the first housing portion 11 has the consequence that the engagement between the retaining elements 151 provided on the stent 150 and the retaining elements 16 of the stent holder 15 is lost, leading to a now complete release of the stent 150 as well (see Fig. 10d) and correspondingly to a complete unfolding of the heart valve prosthesis attached to the stent 150.

**[0156]** Figures 3a to 3d show the trans-apical insertion system 100-1 for different functional states previously defined with reference to Figures 4a to 4d, whereby the depiction now starts with the fourth functional state (see Fig. 3a) and ends via the third functional state (see Fig. 3b) and the second functional state (see Fig. 3c) with the first functional state (see Fig. 3d). The sequence shown in Fig. 3 is used to make clear a procedure with which a stent 150 shown for example in Fig. 10 in the catheter tip 10-1 of the trans-apical insertion system 100-1 is used.

**[0157]** The loading process, as is shown in steps in Figures 3a to 3d, corresponds in reverse to the procedure shown in Fig. 4a to 4d for releasing a stent 150 accommodated in the catheter tip 10-1 of the trans-apical insertion system 100-1. To avoid repetition, reference will be made to the details in Figures 4a to 4d.

**[0158]** Fig. 1 shows an embodiment of a trans-apical insertion system 10-1 in an enlarged representation in its first functional state in accordance with Fig. 3d and Fig. 4a. In particular, separate longitudinal displacement strokes that can be effected with the first and second operating means 71 and 81 are indicated in Fig. 1. It can be seen that the longitudinal displacement stroke of the second operating means 81 between the first stop 85 and the second stop 86 is a total of approx. 16 mm for the embodiment shown. It can be further seen the total longitudinal displacement stroke that can be effected with the first operating means 71 is approx. 37 mm. The overall longitudinal displacement stroke is divided by the stop element 77' provided removably on the first guide 72 into two separate displacement strokes. For the insertion system 100-1, a longitudinal displacement of 24 mm of the first housing portion 11 (stent sheath) relative to the stent holder 15 is provided for the transition from the first functional state into the second functional state. On transition from the third functional state into the fourth functional state of the insertion system 100-1, i.e. after removal of the stop element 77' from the first operating means 71, a subsequent (further) longitudinal displacement of a total of approx. 13 mm of the first housing portion 11 is provided relative to the stent holder 15.

**[0159]** Because of the fact that, with the trans-apical insertion system 100-1, the handle 70-1 has on the one

hand a first and a second stop 85, 86, which are each associated with the second operating means 81 and are designed to define the total longitudinal displacement stroke of the second housing portion 21 (stent funnel) of the catheter tip 10-1 that can be effected on actuation of the second operating means 81 and, on the other hand, has a first, second and third stop 75, 76 and 77 which are each associated with the first operating means 71 and are designed to define the total longitudinal displacement stroke of the first housing portion 11 (stent sheath) of the catheter tip 10-1 that can be effected on actuation of the first operating means 71, the insertion system 100-1 is implemented so that the respective housing portion 11, 21 of the catheter tip 10-1 can be manipulated according to a previously definable sequence of events, for example to allow the release of a stent mounted or mountable in the catheter tip 10-1 at the implantation location to be carried out almost "automatically" without the doctor carrying out the treatment having to have a special skill for, in particular, positioning and fixing the stent at the implantation site.

**[0160]** The previously definable sequence of events for release of the stent mountable in the catheter tip 10-1 at the implantation location is obtained with the embodiment of the trans-apical insertion system, for example, in Figures 1 to 4, in particular by provision of the third stop 77 associated with the first operating means 71 in the form of a stop 77' releasably fastened on the first guide 72 of the first slide 74 forming part of the first operating means 34. This third stop 77 cooperates with the first stop 75 on one side and with the second stop 76 on the other side so that, on actuation of the second operating means 71, a stepwise longitudinal displacement of the first housing portion 11 of the catheter tip 20, consisting of two defined individual steps, can be effected relative to the stent holder 15 in the catheter tip 10-1. In particular, the first and third stop 75, 77 on one side and the second and third stop 76, 77 on the other side define the longitudinal displacement stroke of the first housing portion 11 of the catheter tip 20 that can be effected on actuation of the first operating means 71.

**[0161]** The longitudinal displacement strokes specified in Fig. 1 are indicative examples, which can of course be altered depending on the individual case and are particularly dependent on the size of the stent to be accommodated in the catheter tip 10-1 of the insertion system 100-1.

**[0162]** Fig. 2 shows the trans-apical insertion system 100-1 in accordance with Fig. 1 in a part-sectioned representation, to allow the mechanics of the respective operating means 71 and 81 to be explained more clearly. As is shown, the first operating means 71 exhibits the first slide 74 guided in the first guide 72 and functionally connected with the first pusher 73. This first slide 74 is functionally connected to the first housing portion 11 (stent sheath) of the catheter tip 10-1 associated with the first operating means 71 by means of the first force transmission means 31 of the catheter system 30-1 so that,

on actuation of the first operating means, and in particular the first slide 74, it is possible to transmit a force directly from the first slide 74 to the first housing portion 11 (stent sheath) of the catheter tip 10-1.

**[0163]** Further, it can be seen from the representation in Fig. 2, that the third stop 77 associated with the first operating means 77 is in the form of a stop element 44 releasably fastened on the first guide of the first slide 74.

**[0164]** In relation to the second operating means 81, in the embodiment of the trans-apical insertion system 10-1 according to Figures 1 to 4 it is provided that the second operating means 81 has a second slide 84 guided in a second guide 82 and functionally connected to the second pusher 83. This second slide 84 is functionally connected with the second housing portion 21 (stent funnel) of the catheter tip 10-1 associated with the second operating means 81 by means of the second force transmission means 41 already mentioned so that, on actuation of the second operating means 81, and in particular of the second slide 84, force can be directly transmitted from the second slide 84 to the second housing portion 21 of the catheter tip 10-1.

**[0165]** The securing element 79, 89 associated with the respective operating means 71 and 81 co-operate with the respective pushers 73, 83 of the operating means 71, 81 so that, on the one hand, a longitudinal displacement of the associated second slide 84 that can be effected with the second operating means 81, consequently producing a longitudinal displacement of the second housing portion 21 of the catheter tip 10-1 and, on the other hand, a longitudinal displacement of the associated first slide 74 that can be effected with the first operating means 71, consequently producing a longitudinal displacement of the first housing portion 11 of the catheter tip 20, can be blocked. The respective securing elements 79 and 89 can each be removed from the associated operating means 71 and 81 where required, to transfer the insertion system 100-1 from one functional state into another functional state.

**[0166]** The catheter system 30-1 used with the insertion system 100-1 designed for trans-apical access and depicted in Figures 1 to 4 is described later with reference to Figures 6, 8 and 9.

**[0167]** A procedure for implanting a stent 101 carried out trans-apically is described in more detail in the following with reference to Figures 10a to 10d. A trans-apical insertion system 100-1 of the type described previously is used.

**[0168]** The proximal end region 39 of the catheter system 30-1 with the catheter tip 10-1 is shown in detail in the representation in Fig. 10a, whereby the insertion system 100-1 is in its first functional state (see Fig. 4a). A self-expandable heart valve stent is housed in the catheter tip 10-1. An endoprosthesis, for example, can be used as heart valve stent 150, as shown in Figures 22a to 22c and is described in European Patent Application No. 08 151 963.

**[0169]** As described previously in relation to Fig. 4a,

for example, the insertion system 100-1 in the representation of Fig. 10a is in its first functional state, in which retaining elements 151 (here retaining rings) of this stent 150 are in engagement with retaining elements 16 (here projecting elements) of the stent holder 15, while the retaining hoops 153 of the stent 150 with the heart valve prosthesis which can be attached to them and not explicitly shown in the representation of Fig. 10 are housed in the sleeve-shaped second housing portion 21 (stent funnel) of the catheter tip 10-1.

**[0170]** The positioning hoops 154 of the stent 150 in the first functional state of the insertion system 100-1 are between the sleeve-shaped second housing portion 21 and the similarly sleeve-shaped first housing portion 11 of the catheter tip 10-1, whereby the two housing portions 11, and 21 are arranged to overlap telescopically. In particular, the first housing portion 11 of the catheter tip 10-1 covers the following components: the second retaining region of the stent 150, on which the retaining elements 151 are provided; the positioning hoops 154 of the stent 150; and the sleeve-shaped second housing portion 21 of the catheter tip 10-1.

**[0171]** The (first) retaining region of the stent 150 remote from the retaining elements 151 of the stent 150 is housed in the second housing portion 21 with the retaining hoops 153 and the heart valve prosthesis (not shown in the illustration in Fig. 10).

**[0172]** A shape memory material is preferably used as stent material, whereby the shape memory effect and with it the permanent configuration of the stent 150 is initiated through the effect of an external stimulus. It is particularly preferred that this external stimulus is a definable critical temperature, so that the stent material must be heated to a temperature higher than the critical temperature in the range to initiate the shape memory effect and thus to recover the stored permanent configuration of the stent 150. In relation to the area of use of the insertion system 100-1 described here, it is preferred that the critical temperature is in the range between room temperature and the body temperature of the patient. Thus, when implanting the stent 150, care must be taken that the stent 150 is appropriately cooled, for example by flushing the catheter system 30-1 and the catheter tip 10-1 of the insertion system 100-1 with a suitable coolant, possibly with a saline solution, using an injection adapter 99a provided in the handle 70-1.

**[0173]** The catheter tip 10-1, in the state shown in Fig. 10a, is advanced to the insufficient native heart trans-apically, i.e. approaching from the apex of the heart. Trans-arterial access is also possible, of course, when, instead of the insertion system 100-1 shown in Fig. 10, a trans-femoral or trans-arterial insertion system 100-2, which is yet to be described with reference to Figures 11 to 19, is used.

**[0174]** When the catheter tip 10-1 with the stent 150 accommodated in the catheter tip 10-1 has been advanced to the desired implantation location, cooling is interrupted, with the result that the stent 150 heats up to

the body temperature of the patient (36°C) and consequently the shape memory effect of the stent material is initiated.

**[0175]** Due to the self-expanding characteristic of the stent that is thus initiated, radial forces develop, which act on the individual components of the stent 150 and particularly on the respective positioning hoops 154 and the retaining hoops 153. Since the retaining hoops 153 of the stent 150 are still housed in the sleeve-shaped second housing portion 21 of the catheter tip 10-1, the retaining hoops 153 are held in the folded-up configurations despite initiation of the shape memory effect. The positioning hoops 154 of the stent 150 together with the (first) retaining region of the stent facing the proximal-side end tip 25 of the catheter tip 10-1 are positively held by the sleeve-shaped first housing portion 11 in their folded-up configuration.

**[0176]** After the implantation location has been reached, the positioning hoops 154 of the stent 150 are released, following a suitable stepwise release of the stent from the insertion system 10-1. This is achieved by transferring the insertion system 10-1 from its first functional state (see Fig. 10a) to its second functional state (see Fig. 10b), as has previously been described in detail with reference, for example, to Fig. 4a and Fig. 4b and is shown in Fig. 10b. The first housing portion 11 of the catheter tip 10-1 is moved relative to the stent holder 15 in the proximal direction, and thus away from the handle, by manipulation of the first operating means 71 of the handle 70-1 forming part of the insertion system 100-1. The longitudinal displacement stroke of the sleeve-shaped first housing portion 11 that is effected relative to the stent holder 15 has the result that the positioning hoops 154 of the stent 150 are no longer surrounded and held by the sleeve-shaped first housing portion 11 of the catheter tip 10-1. As a consequence of the self-expanding characteristic of the positioning hoops 15 of the stent, these are opened because of the radial forces acting on them in a radial direction. The opened positioning hoops 154 then positioned in the pockets of the native heart valve.

**[0177]** As already indicated, the catheter tip 10-1 can turn together with the insertion system 100-1 about the longitudinal axis L of the catheter tip 10-1, facilitating the positioning of the unfolded positioning hoops 154 of the stent 150 in the pockets of the native heart valve.

**[0178]** After positioning of the partially expanded stent in the pockets of the native heart valve, the insertion system 100-1 is transferred from its second functional state in accordance with Fig. 10b into its third functional state in accordance with Fig. 10c. The way in which the insertion system 100-1 is transferred from the second functional state into the third functional state has previously been described in detail with reference to Fig. 4c. Fig. 10c shows how the (second) retaining region of the stent 150 remote from the end tip 25 of the catheter tip 10-1 in the third functional state of the insertion system 100-1 is released from the second housing portion 21 of the

catheter tip 10-1. The retaining hoops 153 of the stent 150 and the associated first retaining region of the stent 150 released in the third functional state of the insertion system are stressed because of the radial forces acting on them in the radial direction and consequently a heart valve prosthesis attached to the retaining hoops 153, for example with the aid of a thread etc., unfolds like an umbrella. An example of a heart valve prosthesis 160 attached to the retaining hoops 153 of a stent is shown in Fig. 21.

**[0179]** The function of the already unfolded heart valve prosthesis can be checked in the state shown in Fig. 10c. After the functioning of the heart valve prosthesis has been demonstrated, the insertion system 100-1 can then be transferred - by means of a further manipulation of the first operating means 71 of the handle 70-1 - from its third functional state (see Fig. 10c) into its fourth functional state (see Fig. 10d). The way in which the insertion system 100-1 is transferred into the fourth functional state has been previously described with reference to Fig. 4d. The effect of the transfer of the insertion system 100-1 into the fourth functional state is shown in Fig 10d.

**[0180]** By further displacement of the first housing portion 11 of the catheter tip 10-1 in the proximal direction, and thus away from the handle 70-1, the distal end region of the sleeve-shaped first housing portion 11 of the catheter tip 10-1 is moved further in the proximal direction so that this distal part of the first housing portion 11 no longer covers the retaining elements 16 (here projecting elements) of the stent holder 15. Thus the (second) retaining region of the stent facing the end tip 25 of the catheter tip 10-1 is released from the catheter tip 10-1, so that the second retaining region of the stent 150 also expands, consequently leading to a complete unfolding of the stent 150.

**[0181]** In contrast, if it is found that the implanted heart valve prosthesis cannot or can only inadequately fulfil its function during the check of function of the already unfolded heart valve prosthesis in the third functional state of the insertion system 100-1, in accordance with Fig. 10c, or if the stent 150 is not optimally positioned or cannot be optimally positioned in the implantation site, there is the possibility of retracting the insertion system 100-1 back into the second and then into the first functional state, by moving the corresponding housing portion 11, 21 of the catheter tip 10-1 in the appropriate opposite direction (see depictions in Figures 3b to 3d for this). This allows the already released and expanded components of the stent 150 to be retracted back again into the respective sleeve-shaped housing portion of the catheter tip 10-1, so that the stent 150 housed in the catheter tip 10-1 can be removed from the body of the patient.

**[0182]** As shown in Fig. 10d, the retaining hoops 153 of the stent 150 open in their radial direction on implantation of the stent 150, whereby the radial forces acting on the retaining hoops 153 and also on the second retaining region of the stent 150 result in the stent being pressed against the vessel wall, on the one hand ensur-

ing that the stent 150 with the heart valve prosthesis attached to the first retaining region is securely anchored at the implantation site and, on the other hand, that the heart valve prosthesis is reliably sealed in the first retaining region.

**[0183]** Fig. 5 shows a side elevation of an embodiment of a handle 70-1 for an insertion system 100-1 designed for a trans-apical access. As regards function, the handle 70-1 shown in Fig. 5 is identical to the handle described with reference to Figures 1 to 4. The handle shown in Fig. 5 differs from the embodiment of the handle according to Figures 1 to 4 in that it has an additional grip 88, which projects from the body 70' of the handle 70-1, so with that the doctor carrying out the treatment can hold the handle 70-1 like a pistol.

**[0184]** Preferably, the grip 88 can be connected at different positions with the body 70' of the handle 70-1. Thus it is possible for the grip 88 not to be joined to the underside of the body 70' of the handle 70-1, as indicated in Fig. 5, but to be fastened coming from the above onto the body 70'.

**[0185]** Two injection adapters 99a, 99b are provided for the handle 70-1 shown in Fig. 5. The first injection adapter 99a is located on the longitudinal axis L of the handle 70-1 and is connected to the first pusher of the first operating means 71. The second injection adapter 99b is perpendicular to the longitudinal axis and is connected to the second pusher of the second operating means 71. Where required, a guide wire can be passed to the first injection adapter 99a. The second injection adapter 99b - as is described in more detail subsequently with reference to the illustration in Fig. 6 - is connected to the second slide 84 of the second operating means 81 and is used to supply and drain fluid which can flow via the catheter system 30-1 to the catheter tip 10-1.

**[0186]** Fig. 6 shows a side sectional view of a further embodiment of a handle 70-1 of an insertion system 100-1 which is designed for trans-apical access. The mechanism in the handle 70-1 used in the trans-apical insertion system 101 is described in detail in the following, with reference to the depiction in Fig. 6. The details in the following refer to all handles for a trans-apical insertion system 100-1 described herein.

**[0187]** As shown in Fig. 6, the handle 70-1 has a first and a second operating means 71, 81, which are connected by means of first and second force transmission means 31, 41 of the catheter system 30-1 with the first and second housing portion 11, 21 of the catheter tip 10-1. The first operating means 71 has a first slide 74 guided in a first guide 72 and functionally connected to a pusher knob 73.

**[0188]** In detail, the first pusher knob 73 for the embodiment shown in Fig. 6 comprises a detent spring mechanism with spring elements 90 and catches 91, 92, 93, 94 formed in the first guide 72. As can be seen, particularly in the representation in Fig. 7, which shows a planned view on the handle 70-1 in accordance with Fig. 6, the first pusher knob 73 further comprises at least one

engaging element 95, which is complementary to the catches 91, 92, 93, 94 formed in the first guide 72. The spring elements 90 of the detent spring mechanism designed and co-operate with the first pusher knob 73 on one side and with the first slide 74 on the other so that, in a state when the first operating means 71 is not actuated, the first pusher knob 73 is spaced from the first slide 74 under spring action and engages at least engaging element 95 in one of the catches 91, 92, 93, 94.

**[0189]** In a state when the first operating means 71 is actuated, the first pusher knob 73 is pressed against the spring force of the spring element 90 in the direction of the first slide 74 so that the engagement between the engaging elements 95 and the catches 92, 93, 94 formed complementary to it is released. In this state, the block on longitudinal displacement of the first slide 74 is removed, so that this can be displaced in the direction of the longitudinal axis L of the handle, so that the first of housing portion 11 of the catheter tip 10-1 can be manipulated.

**[0190]** As can be seen in particular in the illustration in Fig. 7, the detent spring mechanism used with the handle 70-1 has first catches 91 and second catches 92, which are each formed complementary to the engaging elements 95 formed on the first slide 74 and arranged at positions spaced from each other in the longitudinal direction of the first guide 72. In this embodiment, in a functional respect the second catches 92 form the first stop 75 used, for example, with the embodiment in accordance with Fig. 1. The first catches 91 formed in the first guide 72 correspond in a functional respect to the third stop 77 in the embodiment of the handle 70-1 shown, for example, in Fig. 1. Thus the distance between the first catches 91 and the second catches 92 defines the longitudinal displacement stroke of the first housing portion 11 of the catheter tip 10-1 that can be affected on actuation of the first operating means 71.

**[0191]** It is particularly preferred that the first and second catches are provided in a first guide surface 72 of the first guide 72, while the detent spring mechanism further has third and fourth catches 93, 94, which are respectively formed complementary to the engaging element 95 formed on the first slide 74. As shown in Fig. 7, the third and fourth catches 93, 94 are formed in a second guide surface 72b, which is opposite to the first guide surface 72a. As with the first and second catches 91, 92, the third and fourth catches 93, 94 are arranged at positions spaced from one another in the longitudinal direction L of the first guide 72. In particular, it is provided that the distance between the third and fourth catches 93, 94 is chosen to be different from the distance between the first and second catches 91, 92. In this way, it is possible to realise different longitudinal displacement strokes of the first housing portion 11 of the catheter tip 10-1 with one and the same first operating means 71. For this, it is only necessary to use the first slide 74 when turned through 180° in the first guide 72. The provision of different longitudinal displacement strokes that can

be realised with the first operating means 71 has the advantage that cardiac valve stents of different length can be implanted with the insertion system 100-1.

**[0192]** The second operating means 81 of the handle 70-1 shown, for example, in Fig. 6 has a second pusher knob 83, which can also be provided with a detent spring mechanism. The second pusher knob 83 is guided in a second guide 82 and is functionally connected to a second slide 84. The second slide 84 is connected by means of the second force transmission means 41 to the second housing portion 21 of the catheter tip 10-1 so that, on actuation of the second operating means 81, force can be transmitted from the second slide 84 to the housing portion 21 of the catheter tip 10-1.

**[0193]** As also previously explained with the handle described, for example, with reference to Figures 1 to 4, the second slide 84 of the second operating means 81 can be moved between a first stop 85 and a second stop 86. When - as with the first operating means 71 - a detent spring mechanism is also used with the second operating means 81, it is possible to do without the stops 85 and 86.

**[0194]** A grip 88 is further connected to the body 70' of the handle 70-1 with the handle 70-1 described in Fig. 6. This grip 88 is releasably fastened to the body 70' and in particular can also be connected to the body 70' from the upper side of the handle 70-1. Corresponding brackets 88' are provided for the purpose in the body 70' (see also the illustration in Fig. 7).

**[0195]** An embodiment of a catheter system is 30-1 used in an insertion system 100-1 designed for trans-apical access is described in more detail in the following, with reference to the illustrations in Figures 6, 8 and 9.

**[0196]** As can be seen in particular in the Fig. 9, which shows the catheter system 30-1 of the insertion system 100-1 designed for trans-apical access in a cross-sectional view, the catheter system 30-1 comprises a first force transmission means 31, which can be connected at its distal end region to the first operating means 71 of the handle 70-1 and that its proximal end region with the first housing portion of the catheter tip 10-1. The first force transmission means 31 is designed to transfer a tensile or shear force to the first housing portion 11 of the catheter tip 10 on actuation of the first operating means 71.

**[0197]** In detail, with the catheter system 30-1 of the insertion system 100-1 designed for a trans-apical access, it is provided that the first force transmission means 31 is formed by a capillary extending from the proximal end region to the distal end region of the catheter system 30-1, through which a guide wire can be passed.

**[0198]** As can be seen in particular in the depiction in Fig. 6, the first force transmission means 31 is in the form of an inner catheter, which is permanently attached to the first slide 74 of the first operating means 71. The first force transmission means 31 merges into the first injection adapter 99a in the distal direction from the first slide 74. This first injection adapter 99a is also permanently connected to the first slide 74 of the first operating means 71 and can be displaced in the longitudinal direction L of

the handle 70-1 relative to the body 70' of the handle 70-1 on actuation of the first operating means 71.

**[0199]** The catheter system 30-1 used with the insertion system 100-1 designed for trans-apical access further exhibits the second force transmission means 41 already mentioned, which is connected on one side to the second slide 84 of the second operating means 81 and on the other side to the second housing portion 21 of the catheter tip 10-1 and is used for transmission of tensile and compressive forces. It can be seen in particular in the illustration in Fig. 6 that, with the catheter system 30-1 for the trans-apical insertion system 100-1, the second force transmission means 41 is implemented as an outer catheter, within which the first transmission means 31, which has already been mentioned, runs in the form of the inner catheter. In detail, the distal end region of the second operating means 41 in the form of the outer catheter is mounted in a positive and force-locking connection between a screw cap 84' screwed on the second slide 84, ensuring a secure fixing of the distal end region of the second force transmission means 41 on the second slide 84.

**[0200]** It can be seen, particularly in the illustration in Fig. 9, that the space between the second force transmission means 41 in the form of the outer catheter and the first force transmission means 31 in the form of the inner catheter is occupied by a filler material, in order to form a filler body. The first transmission means 31 in the form of the inner catheter is passed through this filler body so that, on actuation of the first operating means 71, the first force transmission means 31 in the form of the inner catheter is displaced relative to the filler body 40 in the longitudinal direction L of the catheter system 30-1.

**[0201]** The filler body is preferably made of a plastic filler material that ensures that the of the catheter system 30-1 has the rigidity that is necessary for the trans-apical insertion system 100-1.

**[0202]** Furthermore, it can be seen from the illustration in Fig. 9 that several fluid channels 43 can be formed in the filler body 40. These fluid channels are connected on one side to the second injection adapter 99b (see Fig. 6) and on the other side to the catheter tip 10-1 (see Fig. 8), to ensure that the catheter system 30-1 and catheter tip 10-1 can be flushed through and that fluid can be supplied and drained.

**[0203]** Fig. 6 shows that the filler body 40 is permanently connected to the body 70' of the handle 70-1. The opposing proximal-side end of the filler body 40 is connected permanently to the distal end of the catheter tip 10-1 (see Fig 8).

**[0204]** The catheter system 30-1 of the trans-apical insertion system 100-1 further comprises a cannula capillary 45, the distal-side end region of which is connected by means of a fixing 87 to the body 70' of the handle 70-1 and the proximal-side end region of which is connected to the stent holder 15, and consequently the stent holder 15 is basically held at a non-variable distance relative to

the body 70' of the handle 70-1. The first force transmission means in the form of the inner catheter runs through the inside of this cannula capillary 45.

**[0205]** As the illustration in Fig. 8 shows, the first force transmission means 31 in the form of the inner catheter has a spiral-shaped notch at its proximal side end region, with which only the catheter tip 10-1 has a certain degree of flexibility. The proximal-side end region of the first force transmission means 31 in the form of the inner catheter is permanently connected to the proximal-side end tip 25 of the catheter tip 10-1. As already described previously, the proximal-side end tip 25 is connected at its distal end to the housing portion 11 of the catheter tip 10-1 in the form of the stent sheath. When the first operating means 71 is actuated, the first force transmission means is consequently moved relative to the cannula capillary 45 and the filler body 40 as well as relative to the stent holder 15, through which the first housing portion 11 (stent sheath) can be moved in the longitudinal direction L of the catheter tip 10-1.

**[0206]** The second force transmission means 41 is permanently connected to the second housing portion 21 of the catheter tip in the form of the stent funnel at the transition between the catheter tip 10-1 and the second force transmission means 41 in the form of the outer catheter. The second housing portion 21 (stent funnel) and the filler body 40 are also joined together. Through holes are provided at the connection between the stent funnel (second housing portion 21) and the filler body 40, through which fluid inserted into the fluid channels 43 formed in the filler body 40 using the second injection adapter 99b can be passed into the catheter tip 10-1. A corresponding seal 44 is provided for the fluid channels 43 at the proximal-side end of the filler body 40.

**[0207]** It can be further seen from the illustration in Fig. 8 that the stent holder 15 has a proximal configuration in atraumatic form, which reduces the risk of an injury when the catheter tip 10-1 is removed after release of the stent housed in the catheter tip 10-1.

**[0208]** All previously described components can be used with each embodiment of a trans-apical insertion system 100-1.

**[0209]** A description is given in the following, with reference to Figures 11 to 21, of the components of an insertion system 100-2, which is suitable for a trans-arterial or trans-femoral access to the implantation location. During a trans-arterial or trans-femoral access, the catheter tip 10-2 of the insertion system 100-2 is advanced, for example, via the aorta to the implantation site.

**[0210]** Fig. 20 shows schematically an example of how a trans-arterial or trans-femoral access can be gained to the heart of a patient. In the illustration in accordance with Fig. 20, a heart valve stent is advanced with the aid of a special insertion system via the femoral artery to the aortic valve. Embodiments of the special insertion system, which is suitable for trans-arterial or trans-femoral access are described in the following.

**[0211]** The four different functional states of a trans-

femoral insertion system 100-2 are shown in detail in Figures 14a to 14d, to illustrate the procedure for loading a stent into the catheter tip 10-2 of the insertion system 100-2. The respective functional states of the trans-femoral insertion system 100-2 are shown in Figures 15a to 15d to illustrate the release of a stent mounted in the catheter tip 10-2 of the insertion system 100-2.

**[0212]** The embodiment of the insertion system 100-2 suitable for trans-arterial or trans-femoral access differs from the trans-apical insertion system 100-1 previously described with reference to the depictions in Figures 1 to 4 through a modified construction of the catheter tip 10-2 to enable trans-arterial access to the implantation site. Further, in comparison with the trans-apical insertion system 100-1, the insertion system 100-2 designed for trans-arterial or trans-femoral access has both a different handle 70-2 and a different catheter system 30-2.

**[0213]** The handle 30-2 used for the insertion system 100-2 designed for trans-arterial or trans-femoral access essentially differs from the handle 30-1 used for the trans-apical insertion system 100-1 only in its structural layout.

**[0214]** In distinction to the handle 70-1 for the trans-apical insertion system 100-1, the handle 70-2 for the trans-arterial/trans-femoral insertion system 100-2 according to the illustration in Figures 14 and 15 has a wheel rotatably mounted in the handle 70-2 which is functionally connected to the first housing portion 13 (stent sheath) of the catheter tip 10-2 associated with the first operating means 71 via a corresponding first force transmission means 31, so that force can be directly transmitted from the first operating means 71 in the form of the wheel to the first housing portion 11 of the catheter tip 10-2.

**[0215]** In detail, it is provided that, with the first operating means 71 of the handle 70-2 in accordance with Fig. 14 and Fig. 15, the first operating means 71 in the form of the wheel can turn between a first stop and a second stop, in order to execute a definable longitudinal displacement stroke on the first housing portion 11 of the catheter tip 10-2. As with the first operating means of the handle 70-1 used with the trans-apical insertion system 100-1, the first operating means 71 of the handle 70-2 used with the insertion system 100-2 designed for trans-arterial/trans-femoral access is provided with a third stop between the first and second stop which cooperates, on one side with the first stop and on the other up with the second stop so that, on actuation of the first operating means 71, a longitudinal displacement of the first housing portion 11 of the catheter tip 10-2 can be effected relative to the stent holder 15 of the catheter tip 10-2, consisting of two defined separate steps.

**[0216]** With the first operating means 71 used in the form of a wheel, the third stop associated with the first operating means 71 is in the form of a locking element 77' positioned removably in the flow of force between the wheel and the first housing portion 11 of the catheter tip 10-2, interrupting direct force transmission from the wheel to the first housing portion 11 of the catheter tip 10-2. Alternatively, however, it is possible for the third

stop associated with the first operating means 71 to be in the form of a locking element restricting the free rotation of the wheel between the first and the fourth stop.

**[0217]** However, it is of course also possible in principle for the first operating means 71 of the handle 70-2 used with the insertion system 100-2 designed for trans-arterial/trans-femoral access not to be a wheel, but - as with the handle 70-1 of the trans-apical insertion system 100-1 - to be implemented as a pusher mechanism.

**[0218]** In relation to the handle 30-2 that is used with the embodiment of the insertion system 100-2, for example in accordance with the illustrations in Figures 14 and 15, it is provided that - as also with the trans-apical embodiment of the insertion system 100-1 - the second operating means 81 has a second slide 84 guided in a second guide 82 and functionally connected to a second pusher 83. This second slide 84, which is guided in the interior of the handle 70-2 and therefore cannot be seen in the view of Figures 14 and 15, is functionally connected to the second housing portion 21 (stent funnel) of the catheter tip 10-2 associated with the second operating means 81 by means of a second force transmission means 41 so that, on actuation of the second operating means 81, force is directly transmitted from the second slide 84 to the second housing portion 21 (stent funnel) of the catheter tip 10-2.

**[0219]** The second operating means 81 can be displaced between a first position (Pos. 1) and a second position (Pos. 2) in the longitudinal direction of the handle 70-2, whereby the longitudinal displacement stroke that can be thus effected via the second force transmission means 41 is transferred directly to the second housing portion 21 of the catheter tip 10-2. The first and second positions are each defined with the aid of a first and a second stop 85, 86.

**[0220]** A securing element 89 is provided, associated with the second operating means 81, which is removably located on the second guide 82 and which blocks longitudinal displacement of the (second) slide 84 associated with the second operating means 82 when used.

**[0221]** The handle 70-2 which is used with the trans-arterial/trans-femoral insertion system 100-2 of the embodiment shown in Figures 14 and 15 further exhibits a grip 88, which facilitates the operability of the handle 70-2 and in particular the operating conformity of the handle 70-2. A grip 88 of this type can of course also be used with the handle 70-1 which is used with the trans-apical insertion system shown in Figures 1 to 4. The handle 88 is preferably releasably connected to the body 70' of the handle 70-2 and can optionally be fixed at different positions on the body 70' of the handle 70-2.

**[0222]** In relation to the construction of the catheter tip 10-2 which is used, for example, with the insertion system 100-2 shown in Figures 14 and 15 and which allows trans-arterial/trans-femoral access of a stent housed in the catheter tip 10-2 to the implantation location, it can be seen from Figures 14 and 15 that the catheter tip 10-2 - as also the catheter tip 10-1 for the trans-apical insertion

system 100-1 - has a stent holder 15 for releasably fixing of, for example, the second retaining region of a stent that can be housed in the catheter tip 10-2. In comparison with the catheter tip 10-1 of the insertion system 100-1 designed for trans-apical access, the retaining elements 16 of the stent holder in the form of a crown are now provided at the distal end of the stent holder 15.

**[0223]** Further, the catheter tip 10-2 of the insertion system 100-2 designed for trans-arterial/trans-femoral access comprises a mounting device for mounting a heart valve stent, where required, with a heart valve prosthesis fastened to it. In detail, the mounting device of the catheter tip 10-2 consists of a first housing portion 11, particularly for accommodating the positioning hoops of a stent, and a second housing portion 21, in particular for accommodating the heart valve prosthesis fastened to it, when required.

**[0224]** As also with the previously described embodiment of the trans-apical insertion system 100-1, for example, with reference to Figures 1 to 4, the first operating means 71 of the handle 70-2 co-operates in the embodiment according to Figures 14 and 15 with the first housing portion 11 of the catheter tip 10-2 so that, on actuation of the first operating means 11, by transfer of a defined longitudinal displacement stroke, a previously definable longitudinal displacement of the first housing portion 11 can be effected relative to the stent holder 15. On the other hand, with the insertion system according to Figures 14 and 15, the second operating means 81 of the handle 70-2 co-operates with the second housing portion 21 of the catheter tip 10-2 so that, on actuation of the second operating means 81, by transfer of a defined longitudinal displacement stroke, a previously definable longitudinal displacement of the second housing portion 21 of the catheter tip 10-2 relative to the stent holder 15 can be effected.

**[0225]** In distinction to the trans-apical insertion system 100-1 described with reference to Figures 1 to 4, the second housing portion 21 (stent funnel), which is used to house the retaining hoops of the stent with, where required, the heart valve prosthesis fastened to them, is located at the proximal end region of the catheter tip 10 to in the trans-arterial/trans-femoral insertion system 100-2, for example in accordance with Figures 14 and 15, while the first housing portion 11 (stent sheath) is located between the second housing portion 21 and the handle 70-2.

**[0226]** In the insertion system 100-2 shown in Figures 14 and 15, which is designed for trans-arterial access to the insufficient or stenosed native heart valve, the second force transmission means 41, which connects the second operating means 81 of the handle 70-2 to the second housing portion 21 (stent funnel) of the catheter tip 10-2, is preferably in the form of an inner catheter running inside the interior of the catheter or tube system. The first force transmission means 31, which connects the first operating means 71 of the handle 70-2 to the first housing portion 11 (stent sheath) of the catheter tip 10-2, is in the

form of an outer catheter, in the interior of which the first force transmission means 31 runs in the form of the inner catheter.

**[0227]** On actuation on the second operating means 81, the second housing portion 21 (stent funnel) can be moved relative to the stent holder 15 in the longitudinal direction L of the catheter tip 10-2 in a proximal direction, thus away from the handle 70-2, while, on actuation of the first operating means 71 of the handle 70-2, the first housing portion 11 of the catheter tip 10-2 can be moved relative to the stent holder 15 in the longitudinal direction L of the catheter tip 10-2 in a distal direction, and thus towards the handle 70-2.

**[0228]** The manipulations of the respective housing portions 11, 21 of the catheter tip 10-2 that can be effected on actuation of the respective operating means 71, 81 with the insertion system of 100-2 designed for trans-arterial/trans-femoral access in accordance with Figures 14 and 15 are described in detail in the following, with reference in particular to Figures 15a to 15d.

**[0229]** An embodiment of a trans-arterial/trans-femoral insertion system 100-2 is shown in its four different functional states in Figures 15a to 15d. In detail, the insertion system 100-2 is shown in its first functional state in Fig. 15a, in which the catheter system 30-2 with the catheter tip 10-2 and, where required, with the stent accommodated in it can be inserted into the patient trans-arterially or trans-femorally and advanced via the aorta to the implantation site.

**[0230]** In the first functional state of the insertion system 100-2 in accordance with Fig. 15a, the catheter tip 10-2 is completely closed, whereby the two sleeve-like housing portions 11, 21 of the catheter tip 10-2 overlap telescopically. The respective diameters of the sleeve-like housing portions 11, 21 are chosen so that the folded-up retaining hoops of a stent, with the heart valve prosthesis fastened to them where required, can be housed in the second housing portion 21. The folded-up positioning hoops of the stent housed between the sleeve-shaped element of the second housing portion 21 and the sleeve-shaped element of the first housing portion 11 and are held together in their folded form.

**[0231]** The second retaining region of the stent is shown in the first functional state of the insertion system 100-2, as shown in Fig. 15a, with the stent holder 15 fixed at the distal end of the catheter tip 10-2. For this purpose, the retaining elements (retaining rings etc.) provided at the second retaining region of the stent are engaged with retaining elements 16 of the stent holder 15.

**[0232]** The retaining elements 16 of the stent holder 15 are covered by the sleeve-shaped element of the first housing portion 11 of the catheter tip 10-2 in the first functional state shown in Fig. 15a, so that an engagement between retaining elements provided on the second retaining region of a stent and retaining elements 16 of the stent holder 15 would be possible.

**[0233]** The first functional state of the insertion system 100-2 shown in Fig. 15a is maintained during the trans-

arterial insertion procedure. On reaching the implantation location, the insertion system 100-2 is transferred from the first functional state shown in Fig. 15a to the second functional state shown in Fig. 15b, by transferring the first operating means (shown in the embodiment of the wheel in Fig. 15) from the first position into the second position. The longitudinal displacement stroke transferred by actuation of the first operating means 71 to the first housing portion 11 of the catheter tip 10-2 effects a displacement of the sleeve-like first housing portion 11 relative to the stent holder 15 in the distal direction, thus towards the handle 70-2.

**[0234]** The longitudinal displacement stroke executed on the first housing portion 11 of the catheter tip 10-2 during the transition from the first functional state (see Fig. 15a) to the second functional state (see Fig. 15b) by the first operating means 71 of the handle 70-2 via a corresponding first force transmission means 31 is previously defined so that the sleeve-shaped first housing portion 11 is displaced relative to the stent holder 15 in the distal direction just so far that the positioning hoops of a stent housed in the catheter tip 10-2 would be released, though the proximal end of the first housing portion 11 of the catheter tip 10-2 would still cover the retaining elements 16 of the stent holder 15, so that the engagement between the retaining elements provided at the second retaining region of the stent and the retaining elements 16 of the stent holder 15 would be secure.

**[0235]** Since the second housing portion 21 is not manipulated during the transition from the first functional state into the second functional state, the first retaining region of a stent housed in the catheter tip 10-2 with the heart valve prosthesis fastened to it would continue to be housed in its folded together state in the sleeve-shaped element of the second housing portion 21.

**[0236]** The positioning hoops of a stent housed in the catheter tip 10-2 released in the second functional state of the insertion system 100-2 are opened as a result of the radial forces acting on them and can thus be positioned in the pockets of the insufficient native heart valve. Following appropriate positioning of the positioning hoops of the stent in the pockets of the native heart valve, the insertion system 100-2 is transferred from the second functional state shown in Fig. 15b into the third functional state shown in Fig. 15c. This is done by manipulation of the second operating means 81, after the securing element 89 associated with the second operating means 81 has been removed.

**[0237]** On actuation of the second operating means 81, the second housing portion 21 of the catheter tip 10-2 associated with the second operating means 81 is moved relative to the stent holder by a previously established longitudinal displacement stroke defined with the second operating means 81 in a proximal direction, thus away from the handle 70-2. The longitudinal displacement stroke acting on the second housing portion 21 is chosen so that the sleeve-like second housing portion 21 no longer covers the first retaining region of a stent housed in

the catheter tip 10-2 with the heart valve prosthesis fastened to it, where required, and thus releases the first retaining region of the stent. Due to the action of the radial forces, the proximal retaining region of the stent with the heart valve prosthesis attached to it, where required, unfolds completely.

**[0238]** Since the first operating means 71 of the handle 70-2 and the associated first housing portion 11 of the catheter tip 10-2 are not manipulated during the transition from the second functional state in accordance with Fig. 15b into the third functional state in accordance with Fig. 15c, the proximal end region of the sleeve-shaped first housing portion 11 continues to cover the retaining elements 16 of the stent holder 15, so that the engagement between the retaining elements of a stent housed in the catheter tip 10-2 and the retaining elements 16 of the stent holder is secure and the distal retaining region of the stent is in its folded-up state. This anchorage of the stent to the catheter tip 10-2 of the insertion system allows an explantation of a stent that is already partially unfolded by returning the insertion system 100-2 from the third functional state, by appropriate manipulation of the second operating means 81 of the handle 70-2, to the second functional state and then by suitable actuation of the first operating means 71 transfer to the first functional state.

**[0239]** If an explantation of the stent with the heart valve prosthesis attached to it, where required, is unnecessary, the insertion system 100-2 is transferred from the third functional state shown in Fig. 15c into the fourth functional state shown in Fig. 15d, by turning the first operating means 71 of the handle 70-2 further from the second position to the third position after removal of the securing element 79 (locking element). This manipulation of the first operating means 71 that can be effected after removal of the securing element 79 results in a further defined movement of the first housing portion 11 relative to the stent holder 15 of the catheter tip 10-2 in a distal direction, thus towards the handle 70-2. The longitudinal displacement stroke executed on the first housing portion 11 is chosen so that the proximal end of the sleeve-shaped first housing portion 11 no longer covers the retaining elements 16 of the stent holder 15, as a result of which an engagement between the retaining elements of a stent housed in the catheter tip 10-2 and the retaining elements 16 of the stent holder 15 can be released, which would also lead to a complete release of the second retaining region of the stent and correspondingly to a complete unfolding of the stent.

**[0240]** The four functional states of the insertion system 100-2 designed for trans-arterial/trans-femoral access, previously described with reference to Figures 15a to 15d, are shown in reverse order in Figures 14a to 14d to clarify the procedure for loading a stent into the catheter tip 10-2 of the insertion system 100-2. Comparison between Figures 14a to 14d and Figures 15a to 15d show that the insertion system 100-2 can be loaded with a heart valve stent by transferring the insertion system 100-2, starting from its fourth functional state in accordance with

Fig. 14a (see Fig. 15d), into its third functional state in accordance with Fig. 14b (see Fig. 15c) after a stent has been positioned between the stent holder 15 on the second housing portion 21 with its first retaining region in the direction of the second housing portion 21. Then the remaining functional states of the insertion system 100-2 are taken up in steps until the insertion system 100-2 shown in Fig. 14d is finally in its first functional state with the closed catheter tip 10-2.

**[0241]** A further embodiment of an insertion system 100-2 designed for trans-arterial/trans-femoral access is shown in its first functional state in Fig. 11a. In principle, this embodiment is identical in structural and functional respects to the embodiment shown in Figures 14 and 15. In relation to the handle 70-2 of the insertion system 100-2 shown in Fig. 11a, it can be seen that the end region of the handle 70-2 is in the form of a turning mechanism 98 (rotatable means), with which the second force transmission means 41 of the catheter system 30-2 can be twisted with the proximal-side end tip 25 and the second housing portion 21 (stent funnel) of the catheter tip 10-2 fastened to it about the longitudinal axis L of the catheter tip 10-2. The second housing portion 21 (stent funnel) of the catheter tip 10-2 is connected by means of a loose bearing to the stent holder 15, allowing transmission of a turning moment between the second housing portion 21 and the stent holder 15, without allowing transmission of any tensile or compression forces acting in the direction of the longitudinal axis L of the catheter tip 10-2. Thus, when a turning movement of the second housing portion 21 is induced with the turning mechanism 98, the stent holder 15 also turns correspondingly about the longitudinal axis L.

**[0242]** The turning mechanism 98 preferably allows the stent holder 15 to twist through approx. 120°. Thus the rotation of a stent housed in the catheter tip 10-2, and particularly the positioning hoops already released in the second functional state of the insertion system 100-2, can be controlled, facilitating precise positioning of the already expanded positioning hoops of the stent in the pockets of the insufficient, native heart valve.

**[0243]** Preferably, the rotation movement of the stent holder 15 about the longitudinal access L of the catheter tip 10-2 that can be effected with the turning mechanism 98 exhibits a previously definable, preferably small delay in reaction to a turning moment initiated by means of the turning mechanism 98.

**[0244]** Further, the embodiment of the handle 70-2 shown in Fig. 11a is equipped with a third operating means 96 in the form of a wheel, with which a flexural link 34, preferably provided at the proximal end region of the catheter system 30-2, can be deflected.

**[0245]** The deflection of the proximal end region of the catheter system 30-2 that can be effected with this flexural link region 34 is shown schematically in Fig. 11b. In detail, a device is provided for force transmission (control wire 35 - see Fig. 19) which is connected on one side to the flexural link regions 34 preferably provided at the

proximal end region of the catheter system 30-2 and, on the other side, to the third operating means 96 of the handle 70-2 implemented in the embodiment shown in Fig. 11 as a hand wheel.

**[0246]** As can be seen in the illustration in Fig. 19, it is possible to implement the device for force transmission as a control wire 35, which is passed through the inside of the first transmission means 31 in the form of the outer catheter and preferably at the proximal end of the flexural link region 34 or at the distal end of the catheter tip 10-2 (see Fig. 18) to have a directed effect on the curvature of the flexural link region 34. With the tensile forces that can be exerted on the flexural link region 34 with the aid of the control wire 35, it is possible to obtain a defined curvature of the proximal end region of the catheter system 30-2. This is a particular advantage during trans-arterial/trans-femoral access when navigating the aortic arch.

**[0247]** All embodiments of the insertion system 100-2 designed for trans-arterial/trans-femoral access have a first injection adapter 99a at the distal end of the handle 70-2. As also in the insertion system 100-1 designed for trans-apical access, this first injection adapter 99a is used for flushing the insertion system and as outlet of a guide wire, with the aid of which the actual introduction of the catheter system 30-2 with the catheter tip 10-2 provided at the proximal end of the catheter system 30-2 into the body of the patient is simplified. The catheter system 30-2, the catheter tip 10-2 and the handle 70-2 are thereby threaded into the guide wire and pushed along it, for example into the aorta and to the heart of the patient.

**[0248]** In the embodiments of the insertion system 100-2 designed for trans-arterial/trans-femoral access, a second injection adapter 99b is further provided, by means of which a liquid coolant etc. can be passed via the fluid channels 43 (see Fig. 19) formed in the interior of the catheter system 30-2 to the catheter tip 10-2. With the aid of such a liquid coolant, a stent accommodated in the catheter tip 10-2 can be appropriately cooled while the catheter tip 10-2 is being advanced to the implantation location, as long as the insertion system 100-2 is in its first functional state, in which the catheter tip 10-2 is completely enclosed by the telescopically arranged sleeve-shaped housing portion 11 and 21.

**[0249]** The provision of cooling that can be produced with the second injection adapter 99b for the stent accommodated in the catheter tip 10-2 is a particular advantage when a shape memory material is used as stent material and when the stent can deform under the effect of an external stimulus from a temporary form to a permanent form, whereby the temporary form exists in the first configuration of the stent (in the folded-up state, when the stent is accommodated in the catheter tip 10-2) and the permanent form exists in the second configuration of the stent (in the expanded state of the stent after release of the stent from the catheter tip 10-2).

**[0250]** Further embodiments of an insertion system

100-2 which are suitable for trans-arterial/trans-femoral access to the implantation location are shown in Figures 12 and 13. The respective catheter system is 30-2 and catheter tips 10-2 of the insertion systems 100-2 shown in Figures 12 and 13 are identical in functional and structural respects to systems which have been described previously with reference to Figures 11, 14 and 15.

**[0251]** The embodiment shown in Figures 12 and 13 differs first and foremost in relation to the implementation of the corresponding operating means 71, 81. The handle 70-2, which is used in the insertion system 100-2 shown in Fig. 11, has been described in detail previously with reference to Figures 14 and 15, so that it will not be explained again, to avoid repetition.

**[0252]** The insertion system 100-2 in accordance with Fig. 12 has a handle 70-2 with which the first operating means 71, which is used for manipulation of the first housing portion 11 of the catheter tip 10-2, is similar to a trigger of a revolver. The doctor carrying out the treatment holds the handle at the grip 88, while the first operating means 71 in the form of a trigger of a revolver is operated with the index finger of the hand holding it.

**[0253]** In the insertion system 100-2 shown in Fig. 13, a handle 70-2 is used which corresponds in structural and functional respects to the handle 70-2 used with the insertion system in Fig. 11 with the exception of the grip 88 provided in the embodiment in accordance with Fig. 11.

**[0254]** Fig. 16 shows a part-sectioned representation of a further embodiment of an insertion system 100-2 designed for trans-femoral or trans-arterial access. In particular, the mechanism used in the handle 70-2 of the insertion system 100-2 can be seen with the aid of this illustration. In detail, the handle 70-2 in accordance with the representation in Fig. 16 comprises first and a second operating means 71, 82, which are connected by means of corresponding first and second force transmission means 31, 41 of the catheter system 30-2 yet to be described in detail to the first and second housing portion 11, 21 of the catheter tip 10-2. The first operating means 71 has a first pusher 73 which is functionally connected to the first slide 74. The first slide 74 is guided in a first guide 72 in the longitudinal direction L of the handle 70-2. The proximal-side end of the first guide 72 defines the first stop 75 and the distal-side end of the first guide 72 the second stop 76, which define the overall longitudinal displacement that can be effected with the first operating means 71. A stop element 77' can be positioned between the proximal-side and the distal-side end of the first guide 72, which defines the third stop 77. In principle it is also possible, though, to provide the first operating means 71 with a detent spring mechanism, as has been described previously with reference to Figures 6 and 7.

**[0255]** The second operating means 81 of the handle 70-2 shown in Fig. 16 has a second pusher 83, which is functionally connected to a second slide 84. The second slide 84 is guided in a longitudinal guide (second guide 82) between a first stop 85 and a second stop 86. The

second slide 84 is connected by means of a second force transmission means 41 with the second housing portion 21 of the catheter tip 10-2. On actuation of the second operating means 81, the second slide 84 is moved in the longitudinal direction L of the handle 70-2 from the first stop 85 to the second stop 86. This movement effects a longitudinal displacement of the second housing portion 21 of the catheter tip 10-2 connected via the second force transmission means 41 with the second operating means 81.

**[0256]** To prevent an unintended displacement of the second slide 84, the second operating means is equipped with a removable securing element 89, which connects the second slide 84 with the body 70' of the handle 70-2 when in use. A longitudinal displacement of the second slide 84 to the second stop 86 is only possible following removal of the securing element 89. In principle, it is also possible to equip the second operating means 81 with a detent spring mechanism instead of the securing element 89, as has been previously described with reference to Figures 6 and 7.

**[0257]** Fig. 17 shows a further embodiment of a handle 70-2 of an insertion system 100-2 designed for trans-femoral or trans-arterial access in a part-sectioned side view. The construction and mode of operation of the first and second operating means 71, 81 of the embodiment of the handle 70-2 shown in Fig. 17 is comparable in structural and functional respects to the handle is previously described for the trans-arterial or trans-femoral insertion system 100-2. In distinction to the handle described with reference to Fig. 16, however, the handle in accordance with Fig. 17 is provided with a third operating means 96 in the form of a wheel, by means of which a flexural link region 34 of the catheter system 30-2 can be controlled.

**[0258]** The third operating element 96 preferably has a detent device 100, to allow a set deflection of the flexural link region 34 of the catheter system 30-2 to be fixed. For example, in relation to the detent device 100, it is possible to provide a suitable catch mechanism on the hand wheel of the third operating means 96, which cooperates with the body 70' of the handle 70-2. In particular, it is possible for the flexural link region 34 of the catheter tip 30-2 to be connected to the third operating means 96 by way of a control wire 35 whereby, on an actuation of the third operating means 96 via the control wire 35 a tensile force is exerted on the flexural link region 34, which produces the deflection of the flexural link region 34 (see Fig. 11b).

**[0259]** However it is also possible, of course, to choose another embodiment as the third operating means 96 for deflecting the flexural link region.

**[0260]** It is particularly preferred that the handle 70-2 of the insertion system 100-2 designed for trans-arterial or trans-femoral access is provided with a pretensioning device, shown in Figure. 17, with which a constant tensile force is exerted via the second operating means 81 on the second housing portion 21 of the catheter tip 10-2.

In detail, the pretensioning device shown in Fig. 17 has a compression spring 97, permanently stressed along its spring axis, which is prestressed between a first stop 97a connected to the body 70' of the handle 70-2 and a second stop 97b connected to the distal end region of the second operating means 81, so that a permanent, previously defined or definable tensile force is exerted on the second housing portion 21 of the catheter tip 10.

**[0261]** The pretensioning device implemented with the spring 97 in the embodiment in accordance with Fig. 17 is especially advantageous when the catheter system 30-2 is provided with a flexural link region 34 (see Fig. 11). When the flexural link region 34 is bent, the outer fibres of the catheter system 30-2 are shortened and this can be compensated for appropriately with the aid of the pretensioning device. In detail, on bending of the flexural link region 34 relative to the neutral fibres of the catheter system 30-2 running along the longitudinal axis L, the outer fibres of the catheter system 30-2 radially spaced from the neutral fibres are shortened. Since the second force transmission means 41, which connects the second operating means 81 with the second housing portion 21 in the insertion system 100-2 designed for trans-arterial or trans-femoral access, normally runs along the neutral fibre of the catheter system 30-2, a bending contraction inevitably occurs when the catheter system 30-2 is bent, having the result that, despite fixing of the first operating means 71, the first housing portion 11 of the catheter tip 10-2 is displaced relative to the stent holder 15 in a distal direction.

**[0262]** This longitudinal displacement of the first housing portion 11 of the catheter tip 10-2 that takes place during the bending procedure is compensated with the aid of the prestressing device (spring 97), since the spring 97 of the prestressing device exerts a constant tensile force on the second force transmission means 41 and therefore on the second housing portion 21 of the catheter tip 10-2 and consequently constantly presses the proximal-side end tip 25 of the catheter tip 10-2 against the proximal-side end of the first housing portion 11. This ensures that the catheter tip 10-2 in the first functional state of the insertion system 100-2 (see Fig. 15a) remains completely closed even during a deflection of the catheter system 30-2 effected with the flexural link region 34.

**[0263]** On actuation of the second operating means 81, i.e. when the insertion system 100-2 transfers from its second functional state shown, for example, in Fig. 15b into its third functional state shown, for example, in Fig. 15c, it is necessary to press the second slide 84 against the prestress supplied by the spring 97 of the prestressing device on the second stop 86.

**[0264]** A catheter system 30-2 is described in the following, with reference to the illustrations in Figures 17, 18 and 19, which can be used with an insertion system designed for trans-arterial or trans-femoral access.

**[0265]** The catheter system 30-2 exhibits a first force transmission means 31 in the form of an outer catheter, whereby this first force transmission 31 is used to connect

the first operating means 71 of the handle 70-2 to the first housing portion 11 (stent sheath) of the catheter tip 10-2. As can be seen in particular from the illustration in Fig. 17, the first force transmission means 31 implemented as an outer catheter is clamped between a screw cap 71' and the first slide of the first operating means 71 and consequently is permanently connected to the first slide 74. The proximal-side end region of the first force transmission means 31 in the form of the outer catheter merges into the first housing portion 11 of the catheter tip 10-2 in the form of the stent sheath and is connected to the first housing portion 11 in the form of the stent sheath.

**[0266]** The second force transmission means 41 of the catheter system 30-2 used with an insertion system 100-2 designed for trans-arterial or trans-femoral access is implemented as an inner catheter. The distal-side end region of the second force transmission means 41 implemented as an inner catheter is permanently connected to the second slide 84 of the second operating means 81. The proximal-side end region of the second force transmission means 41 in the form of the inner catheter is connected to the end tip 25 of the catheter tip 10-2. The second housing portion 21 of the catheter tip 10-2 is permanently connected by means of its proximal-side end to the end tip of the catheter tip 10-2 so that, on actuation of the second operating means 81 via the force transmission means 41 in the form of the inner catheter, a tensile or compressive force can be transmitted to the second housing portion 21 of the catheter tip 10-2 in the form of the stent funnel.

**[0267]** As can be seen particularly from the illustration in Fig. 19, the second force transmission means 41 in the form of the inner catheter runs along the neutral fibre of the catheter system 30-2 inside the first force transmission means 31 in the form of the outer catheter. The space between the first force transmission means 31 in the form of the outer catheter and the second force transmission means 41 in the form of the inner catheter is filled with a filler material, so that a filler body 40 is formed. The filler material and is preferably a relatively elastic plastic material to allow the catheter system 30-2 to bend overall and in particular at the flexural link region 34 (see Fig. 11).

**[0268]** Fig. 17 shows that the filler body 40 is connected by means of a fixing 87 to the body 70' of the handle 70-2. The distal-side end region of the stent holder 15 attaches at the proximal-side end region of the filler body 40 (see Fig. 18). The connection between the stent holder 15 and the filler body 40 is preferably chosen so that it allows rotation of the stent holder 15 relative to the filler body 40. This is especially necessary for control of the rotation of the positioning hoops of the already partially released stent during the implantation procedure (see Fig. 21a). On the other hand, the second force transmission means 41 in the form of the inner catheter 41 can be turned about the longitudinal direction L by means of a rotatable cap 98 provided at the distal end region of the handle 70-2. This rotary movement is transferred

from the second force transmission means 41 direct to the end tip 25 of the catheter tip 10-2 and thus to the second housing portion 21 in the form of the stent funnel.

**[0269]** It is particularly preferred that the second force transmission means in the form of the inner catheter runs through the body of the stent holder 15 and cooperates with the stent holder 15 with the aid of a suitable toothing, to transmit a turning moment exerted by means of the rotary cap of the handle 70-2 on the second force transmission means 41 to the stent holder 15, while tensile or compression forces acting in the longitudinal direction L of the catheter tip 10-2 are not transmitted from the second force transmission means 41 in the form of the inner catheter to the stent holder 15.

**[0270]** As can also be seen in the illustration in Fig. 19, a least one fluid channel 43 is provided in the filler body 40 of the catheter system 30-2, connected at its distal-side end to the second injection adapter 99b (see Fig. 17) and at its proximal-side end correspondingly to the catheter tip 10-2, consequently ensuring supply of fluid to the catheter tip 10-2 and draining of fluid from the catheter tip 10-2. Furthermore, a channel 36 to accommodate a control wire 35 is provided in the filler body 40, with which the third operating means 96 cooperates with the flexural link region 34 of the catheter system 30-2 (see Fig. 11 and Fig. 17). In the illustration in Fig. 18, the proximal-side end of the control wire 35 is fixed to the distal-side end region of the stent holder 15.

**[0271]** As already indicated it is possible in principle for the previously described handles 70-1, 70-2, which are suitable either for a trans-apical insertion system 100-1 or for a trans-femoral or trans-arterial insertion system 100-2, to be provided with operating means 71, 81, with which a detent spring mechanism is used, as has previously been described with reference to illustrations in Figures 6 and 7. Externally provided securing elements 79, 89 are then unnecessary.

**[0272]** Furthermore, it is possible in principle to connect one or several grips 88 to the body 70' of the handle 70-1 or 70-2, which are releasably connected to the body 70' and can be plugged in and unplugged as required. It is also possible for the third operating means with the handle 70-2 of the trans-femoral or trans-arterial insertion system 100-2 (see Fig. 17) to be implemented, not as a wheel, but as a pusher.

**[0273]** It is obvious that all the individual features that have been described in connection with the respective handles 70-1 and 70-2 can be combined with one another.

**[0274]** A preferred embodiment of a medical device for treatment of a heart valve stenosis and/or heart valve insufficiency in a patient is described in the following with reference to Figures 21a to 21c. As depicted, the medical device exhibits an insertion system 100-to design for trans-arterial/trans-femoral access, as has been described in detail previously, for example, with reference to Figures 11 to 18. However, it is also possible for the medical device to exhibit an insertion system 100-1 which

it is designed for a trans-apical access, as has been described previously, for example with reference to Figures 1 to 10.

**[0275]** In addition to the insertion system 100-2, the medical device has a self-expandable heart valve stent 150 mounted in the catheter tip 10-2 of the insertion system 100-2, to which a heart valve prosthesis 160 to be implanted is fastened. In the first functional state, not shown, the stent 150 exhibits a first, previously definable configuration, in which it is in its folded-together state. On the other hand, the stent 150 is designed to adopt a second previously definable configuration in the implanted state, in which it exists in its expanded state.

**[0276]** Through the use of the insertion system 100-2 described above, during the implantation procedure, the stent 150 is transferred sequentially, following a previously definable sequence of events in steps from its first previously defined configuration into its second previously defined configuration.

**[0277]** In detail, the stent 150 that is used with the medical device in accordance with the depiction in Figures 21a to 21c exhibits a first retaining region, to which the heart valve prosthesis 160 is attached. Further, the stent comprises a second retaining region with three retaining elements 151, each in the configuration of retaining rings, which can be brought in to a releasable engagement with the retaining elements 16 of the stent holder 15 provided in the catheter tip 10-2.

**[0278]** In addition, the stent 150 has three retaining hoops 153 to accommodate the heart valve prosthesis 160 and three positioning hoops 154 for automatic positioning of the stent 150 at the implantation site, whereby the respective positioning hoops 154 of the stent 150 are designed in functional and structural respects to engage the pockets 170 of the native heart valve during the implantation procedure and in the implanted state of the stent 150, in particular from the second functional state of the insertion system 100-2. In detail, each positioning hoop 154 and its associated retaining hoop 153 has an essentially U or V-shaped structure, which is closed towards the proximal end of the stent 150.

**[0279]** The stent 150, which together with the insertion system 100-2 forms the basis of the medical device, is especially suitable for insertion into the body of a patient with the aid of the insertion system 100-2 with minimal invasiveness. The distinctive feature of the stent 150 is that the three positioning hoops 154 of the stent 150 undertake the function of automatic positioning of the stent 150 with the heart valve prosthesis 160 attached to it in the aorta of the patient. The positioning hoops 154 have radiused head sections, which engage in the pockets 170 of the insufficient heart valve to be replaced by the heart valve prosthesis during positioning of the stent 150 at the implantation site. The provision of a total of three positioning hoops 154 takes care of the necessary positioning accuracy in the rotary direction.

**[0280]** In this state shown in 21a, the catheter tip 10-2 and the catheter system 30-2 of the trans-arterial or trans-

femoral insertion system 100-2 has been inserted by a puncture of the groin artery of the patient and the catheter tip 10-2 has been advanced to the implantation site with the aid of a guide to wire 180. In detail, the insertion system 100-2 to be used is shown already in its second functional state in Fig. 21a. The second functional state of the insertion system 100-2 designed for trans-arterial or trans-femoral access has been described previously, for example with reference to Fig. 15b.

**[0281]** In the second functional state, the sleeve-like first housing portion 11 of the catheter tip 10-2 has already moved by a first predetermined amount of movement in a distal direction, and thus towards the handle, leading to a release of the positioning hoops 154 of the stent 150. These already expanded positioning hoops 154 of the stent shown in Fig. 21a are positioned - where necessary by a suitable rotation of the catheter tip 10-2 - in the pockets 170 of the native heart valve position. After positioning of the positioning hoops 154 in the pockets 170 of the native heart valve is complete, the insertion system 100-2 is transferred from its second functional state (see Fig. 15b) into its third functional state (see Fig. 15c).

**[0282]** The manner in which the insertion system 100-2 is transferred into its third functional state has been described previously, for example with reference to Fig. 15c. Fig. 21b shows the insertion system 100-2 in accordance with Fig. 21a, in which the second sleeve-like housing portion 21 has been displaced in a proximal direction so that the first retaining region of the stent with the retaining hoops 153 and the heart valve prosthesis 160 attached to them are released. These components are opened as a result of the radial forces attacking them, whereby the old heart valves are clamped between the positioning hoops 154 and the retaining hoops 153.

**[0283]** After the functioning of the heart valve prosthesis 160 has been checked, the insertion system 100-2 is then transferred from its third functional state into its fourth functional state, as has previously been described, for example with reference to Fig. 15d. Fig. 21 shows the effect of the transfer of the insertion system 100-2 into its fourth functional state on the heart valve prosthesis 160 and the stent 150.

**[0284]** In detail, it can be seen that, in the fourth functional state of the insertion system 100-2, the first housing portion 11 of the catheter tip 10-2 has been displaced further in a distal direction, as a result of which the anchorage of the retaining elements 151 on the second retaining region of the stent 150 is released. This has the result that that the second retaining region of the stent 150 can also expand and press against the vessel wall.

**[0285]** Finally, the catheter tip 10-2 and the catheter system 30-2 of the insertion system 100-2 is removed again from the body of the patient.

**[0286]** When the heart valve stent 150 is implanted, the old (insufficient) heart valve is pressed against the vessel wall at the same time due to the self-expanding characteristic of the stent on 50, as can be seen in par-

ticular in Fig. 21c. In particular, the semilunar heart valves of the insufficient, native heart valve are clamped between the positioning hoops 154 and the retaining hoops 153 because of the expansion of the stent 150, in addition to which the heart valve prosthesis 160 located on the first retaining region of the stent 150 is optimally positioned and is stably anchored.

**[0287]** In summary, it remains to be said that the solution in accordance with the invention is distinguished by the improved insertion system with the stent mountable in the catheter tip of the insertion system. The stent may be inserted trans-arterially or trans-apically by the special insertion system and can be optimally positioned, so that a heart valve prosthesis sewn on the first retaining region of the stent can undertake the function of the insufficient or stenosed native heart valve. The radial forces developed due to the self-expanding characteristic of the stent ensure a secure anchoring in the area of the aorta. The catheter system of the insertion system is preferably an 18 to 21F introducer, which is compatible with 21F-insertion tubes and a 0.035" guide wire. The length of the catheter system for trans-arterial access should be at least 100 cm. The optionally provided flexural link region at the proximal region of the catheter system is preferably approx. 30 cm.

**[0288]** The solution in accordance with the invention is not limited to the preferred embodiment is described in the attached drawings. On the contrary, combinations of the individual features described in detail are also possible.

## Claims

1. A handle (70) for manipulating a catheter tip (10) of a medical insertion system (100), wherein the handle (70) has at least a first and a second operating means (71, 81), with which first and second portions (11, 21) of the catheter tip (10) can be manipulated (10) so that a self-expandable stent (101) housed in the catheter tip (10) can be released in steps in a previously defined or definable sequence of events from the catheter tip (10), wherein the handle (70) further has at least one stop (75, 76, 77, 85, 86) associated with the operating means (71, 81), which is designed to limit a longitudinal displacement stroke of the first and/or second portion (11, 21) of the catheter tip (10) that can be effected by actuation of the at least one operating means (71, 81).
2. A handle (70) in accordance with claim 1, wherein the handle (70) further has a first stop (75) associated with the first operating means (71) and a second stop (76) associated with the first operating means (71), wherein the first and second stop (75, 76) are designed to limit an overall longitudinal displacement stroke of a first portion (11) of the catheter

tip (10) that can be effected by actuation of the first operating means (71); and wherein the handle (70) has a first stop (85) associated with the second operating means (81) and a second stop (86) associated with the second operating means (81), wherein the first and second stop (85, 86) are designed to limit an overall longitudinal displacement stroke of the second portion (21) of the catheter tip (10) that can be effected by actuation of the second operating means (81).

3. A handle (70) in accordance with claim 2, wherein the handle (70) further has a third stop (77) associated with the first operating means (71), which co-operates with the first stop (75) of the first operating means (71) on the one side and with the second stop (76) of the first operating means (71) on the other side so that, when the first operating means (71) is actuated, a stepwise longitudinal displacement of the first portion (11) of the catheter tip (10), consisting of at least two individual steps, can be effected, wherein the first and third stop (75, 77) of the first operating means (71) on the one side and the second and third stop (76, 77) of the first operating means (71) on the other side determine the longitudinal displacement stroke of the first portion (11) of the catheter tip (10) that can be effected by actuation of the first operating means (71).
4. A handle (70) in accordance with one of the claims 1 to 3, wherein the first operating means (71) has a first carriage (74) guided in a first guide (72) and functionally connected to at least one first slider knob (73), wherein the first carriage (74) can be connected to the first portion (11) of the catheter tip (10), so that when the first operating means (71) is actuated a direct transmission of force can be realised from the first carriage (74) to the first portion (11) of the catheter tip (10).
5. A handle (70) in accordance with claim 3 and claim 4, wherein the third stop (77) is embodied as a stop element releasably fastened to the first guide (72).
6. A handle (70) in accordance with one of the claims 1 to 5, wherein the first and/or the second operating means (71, 81) are/is supported rotatably in the handle (70) and connected to one of the first and second portions (11, 21) of the catheter tip (10).
7. A handle (70) in accordance with one of the claims 1 to 6, wherein the first operating means (71) is supported rotatably in the handle (70) and wherein an engaging element (77) is associated with the first operating means (71) said engaging element (77) being de-

- signed to restrict the ability of the first operating means (71) to rotate freely between the first and the second stop (75, 76) of the first operating means (71).
8. A handle (70) in accordance with one of the claims 1 to 6,  
 wherein the first operating means (71) is supported rotatably in the handle (70) and wherein a locking element is associated with the first operating means (71), said locking element being designed to interrupt a transmission of force from the wheel (78) to the first portion (11) of the catheter tip (10), wherein the locking element is located removably in the force flow between the first operating means (71) and the first portion (11) of the catheter tip (10).
9. A handle (70) in accordance with one of the claims 1 to 8,  
 wherein the handle (70) further has a first securing element (79) removable from the handle (70), which is associated with the first operating means (71) and cooperates with the first operating means (71), so that a longitudinal displacement of the first portion (11) of the catheter tip (10) that can be effected with the first operating means (71) can be inhibited, and/or wherein the handle (70) further has a second securing element (89) removable from the handle (70), which is associated with the second operating means (81) and cooperates with the second operating means (81), so that a longitudinal displacement of the second portion (21) of the catheter tip (10) that can be effected with the second operating means (81) can be inhibited.
10. A catheter system (30) of a medical insertion system (100) for inserting a self-expandable heart valve stent (101) into the body of a patient, wherein the catheter system (30) has first and second force transmission means (31, 41), which is connected for manipulation of first and second portions (11, 21) of the catheter tip (10) on the one side at the proximal end portion of the catheter system (30) with the catheter tip (10) and on the other side at the distal end portion of the catheter system (30) with the first and second operating means (71, 81) of a handle (70) according to one of the claims 1 to 9.
11. A catheter system (30) in accordance with claim 10, wherein the catheter system (30) has a first force transmission means (31), which can be connected at its distal end portion with the at least one first operating means (71) of the handle (70) and at its proximal end portion with the first portion (11) of the catheter tip (10) and is designed to transmit a tensile or shear force to the first portion (11) of the catheter tip (10) when the at least one first operating means (71) is actuated; and wherein the catheter system (30) further has a second force transmission means (41), which can be connected at its distal end portion with the at least one second operating means (81) of the handle (70) and at its proximal end portion with the second portion (21) of the catheter tip (10) and is designed to transmit a tensile or shear force to the second portion (21) of the catheter tip (10) when the at least one second operating means (81) is actuated.
12. A catheter system (30) in accordance with claim 10 or 11,  
 wherein one of the first and second force transmission means (31; 41) has a tubular form and the other force transmission means (41; 31) is mounted in the interior of the one force transmission means (31; 41) at least in sections.
13. A catheter system (30) in accordance with claim 12, wherein the catheter system (30) has a filler body (40) formed from a filler material, which is located between which the one force transmission means (31; 41) and the other force transmission means (41; 31), in a portion of the catheter system (30), in which the other force transmission means (41; 31) is mounted in the interior of the one force transmission means (31; 41).
14. A catheter system (30) in accordance with claim 13, wherein a guide channel (32, 42) is formed in the filler body (40), running in the direction of the longitudinal axis of the catheter system (30), through which the other force transmission means (41; 31) is guided.
15. An insertion system (100) for inserting a self-expandable heart valve stent (101) into the body of a patient, wherein the insertion system (100) has the following:
- a catheter system (30) according to one of the claims 10 to 14, by means of which the stent (101) can be introduced into the body of a patient in its folded-together state;
  - a catheter tip (10) provided at the proximal end portion of the catheter system (30), in which the stent can be received; and
  - a handle (70) provided at the distal end of the catheter system (30) according to one of the claims 1 to 9, with which the first and second portions (11, 21) of the catheter tip (10) can be manipulated.

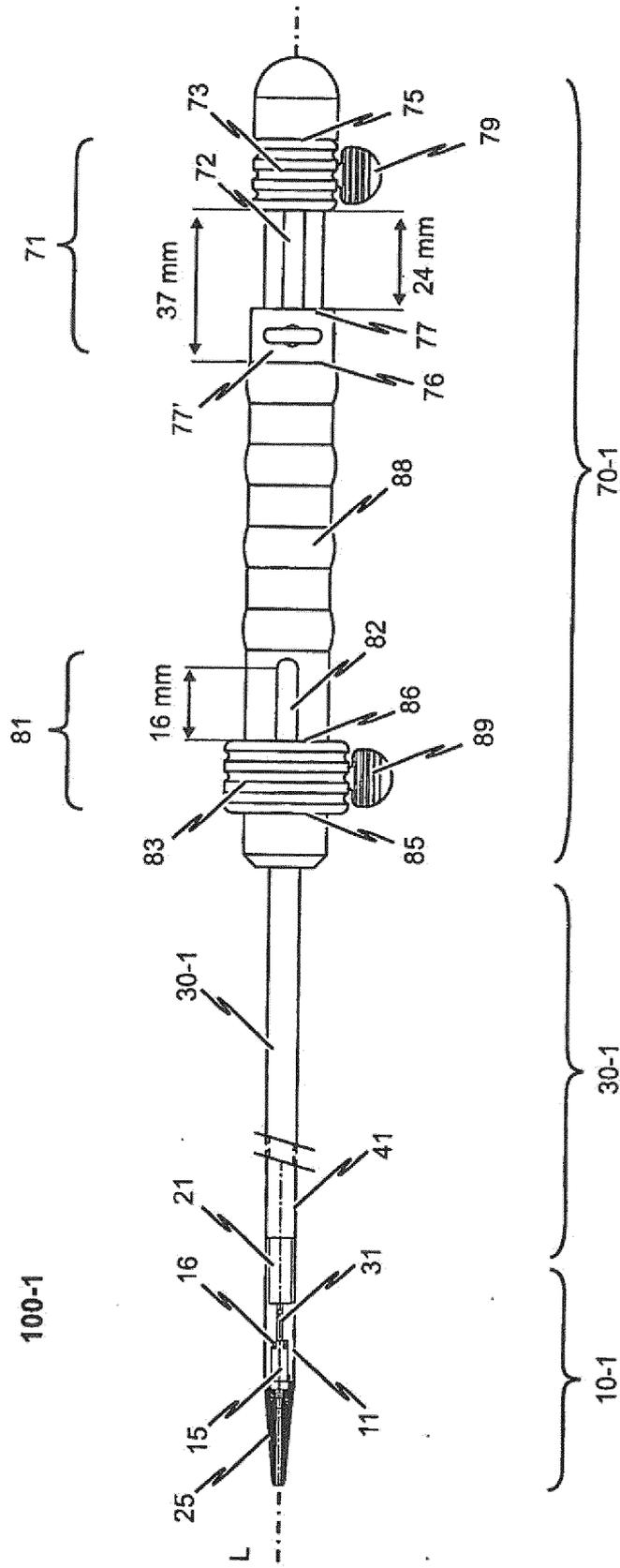


Fig. 1

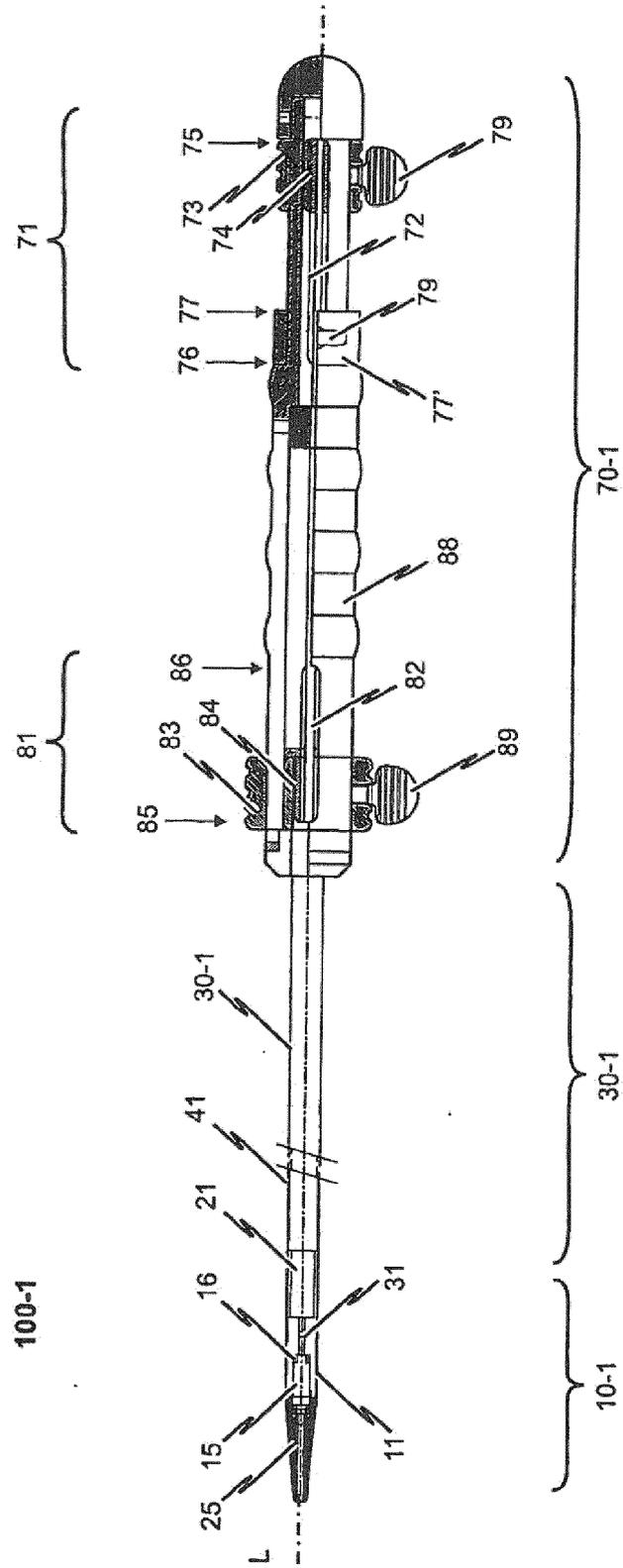
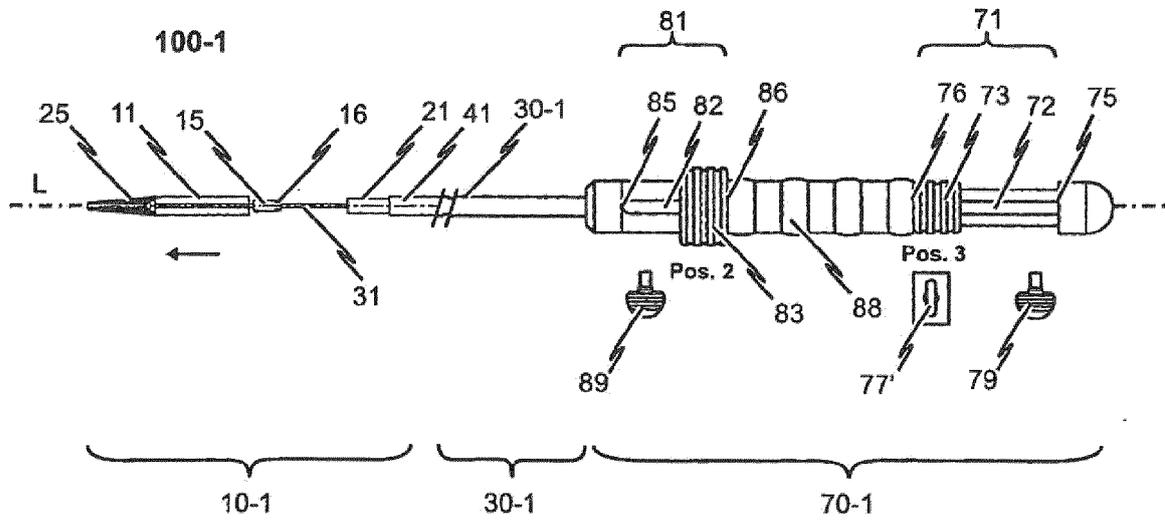
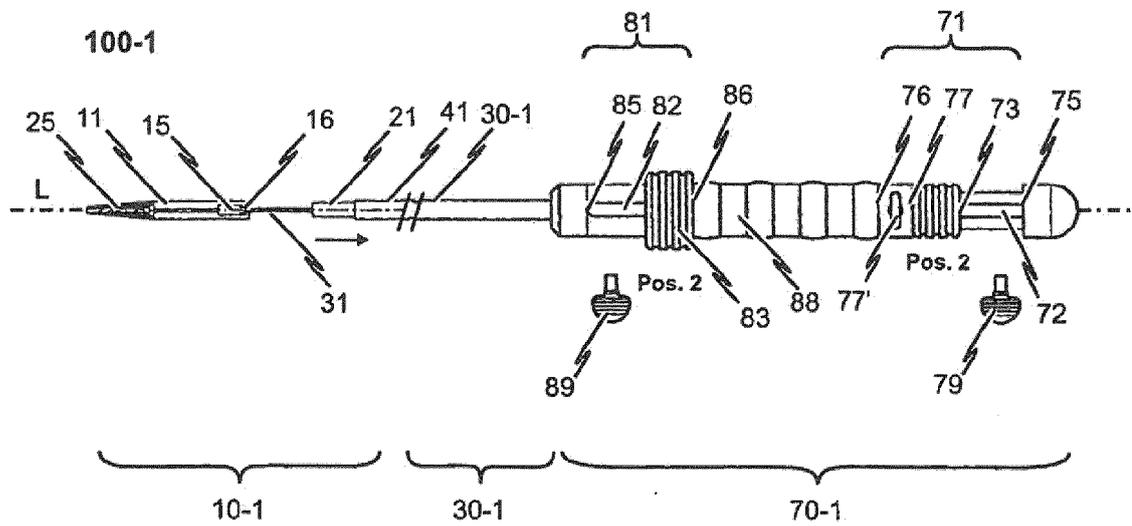


Fig. 2



*Fig. 3a*



*Fig. 3b*

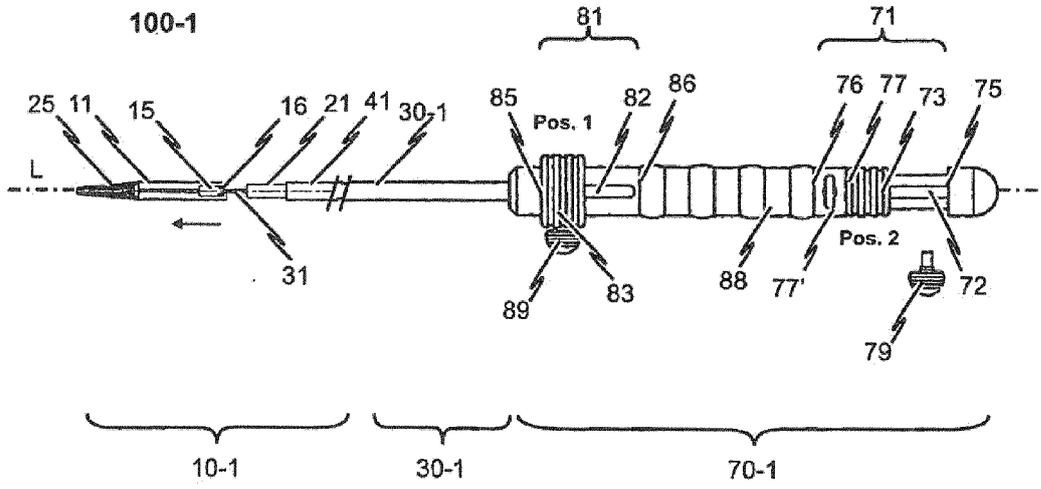


Fig. 3c

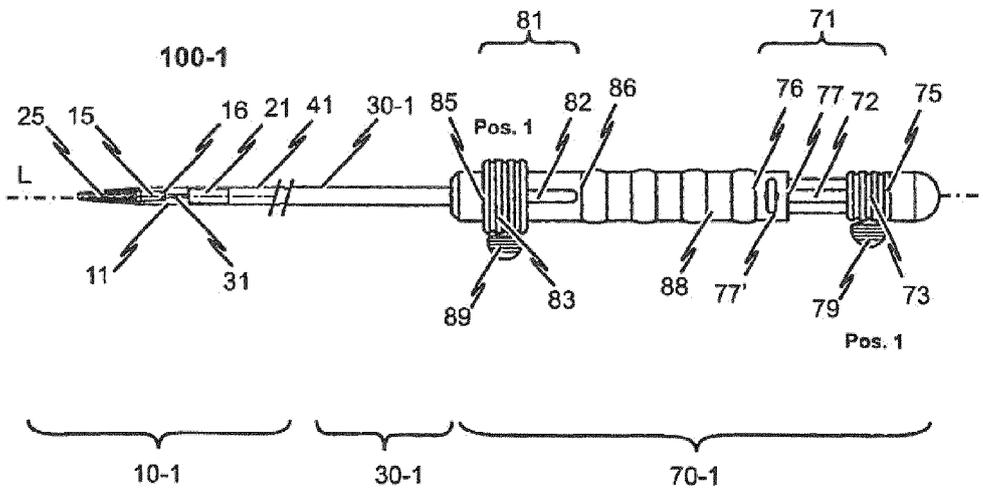
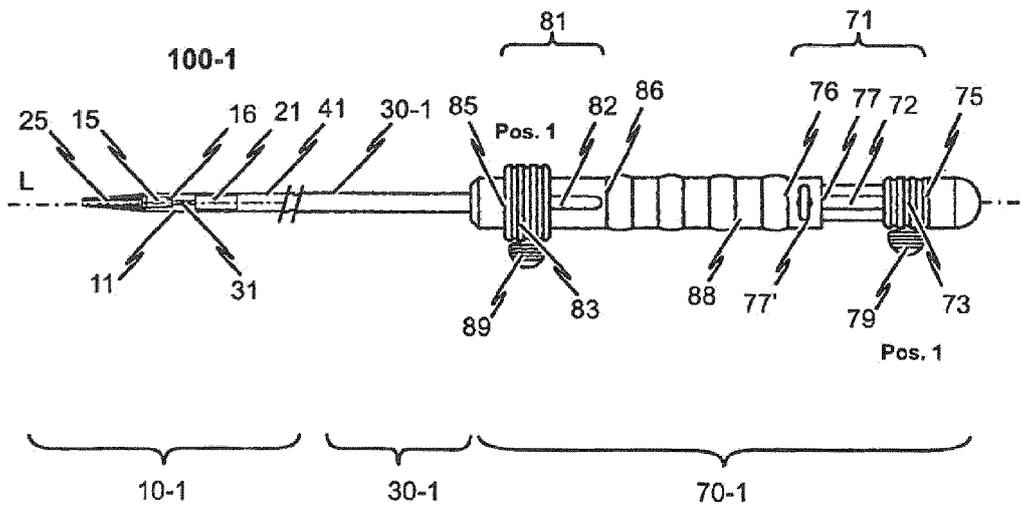
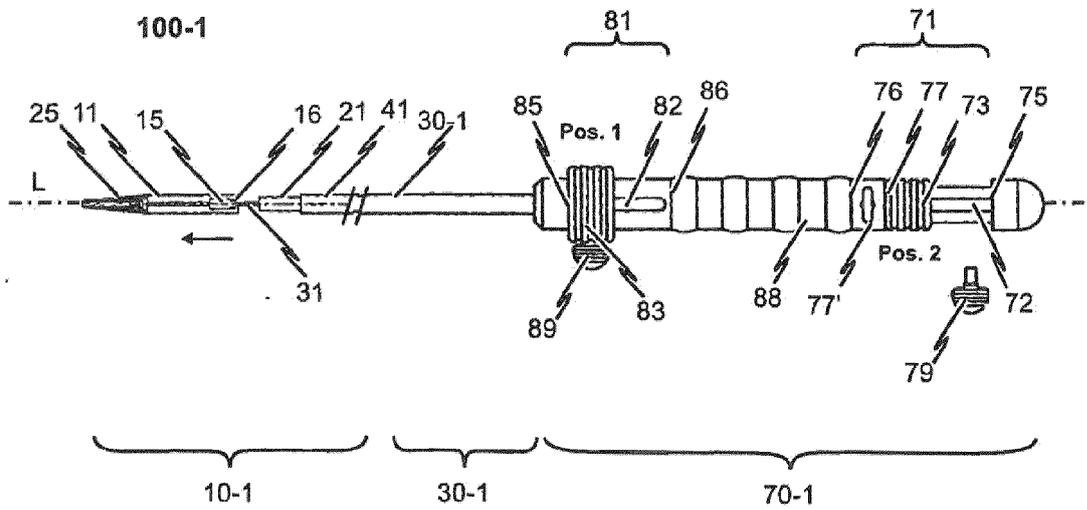


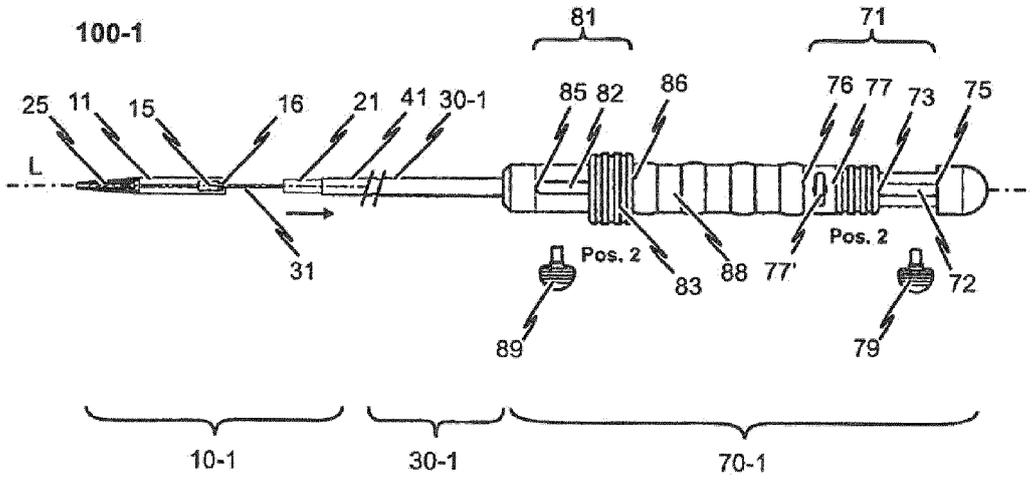
Fig. 3d



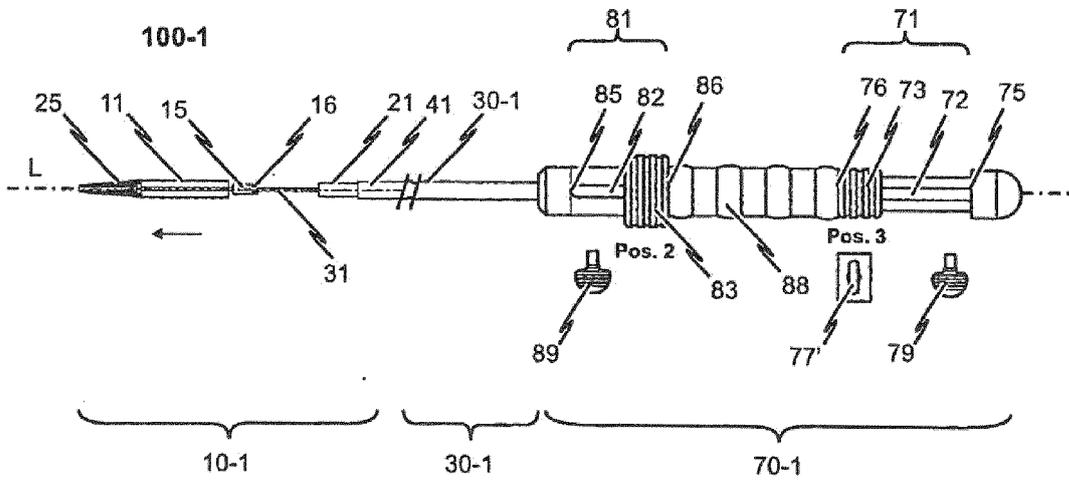
*Fig. 4a*



*Fig. 4b*



*Fig. 4c*



*Fig. 4d*

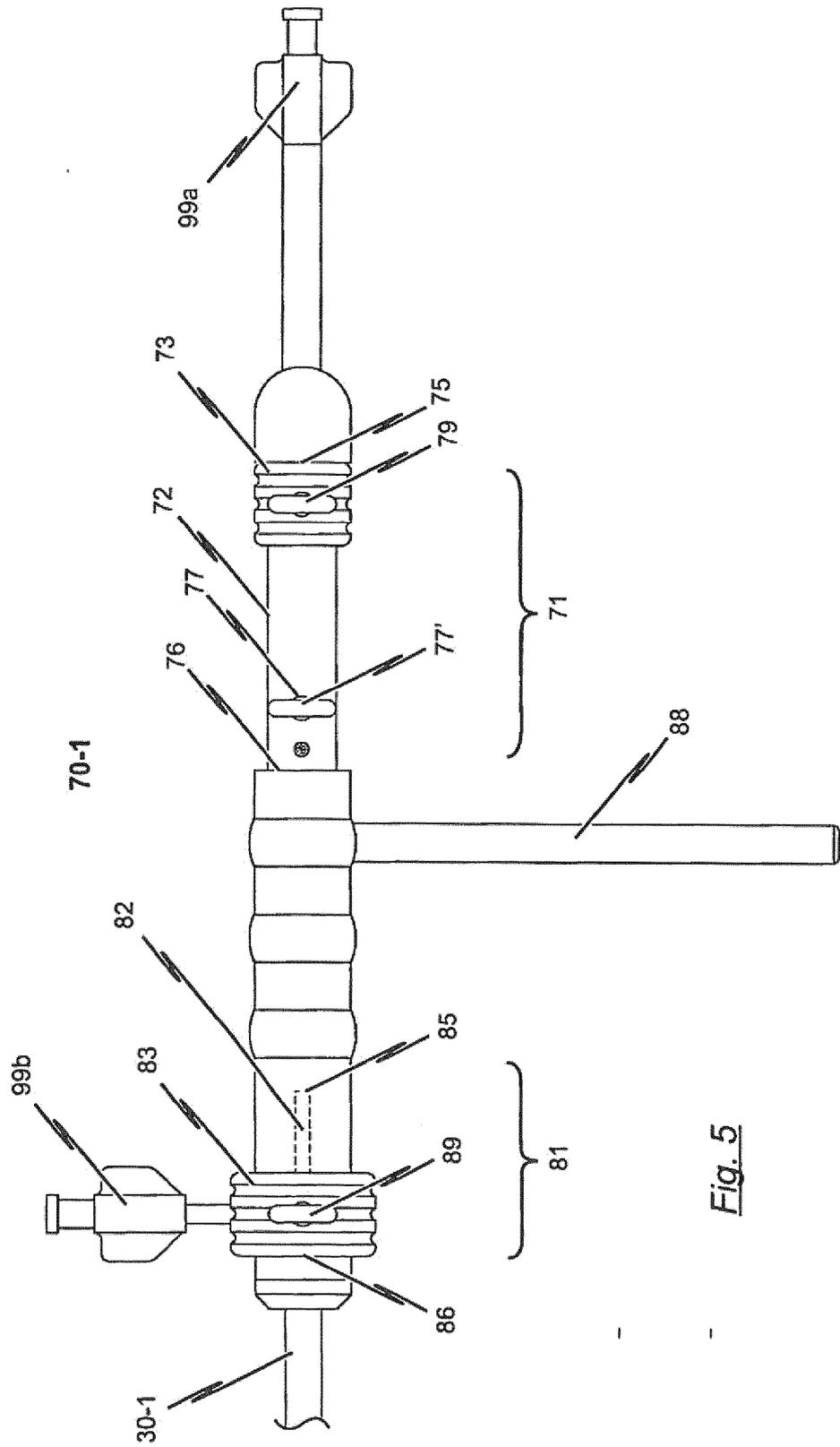


Fig. 5

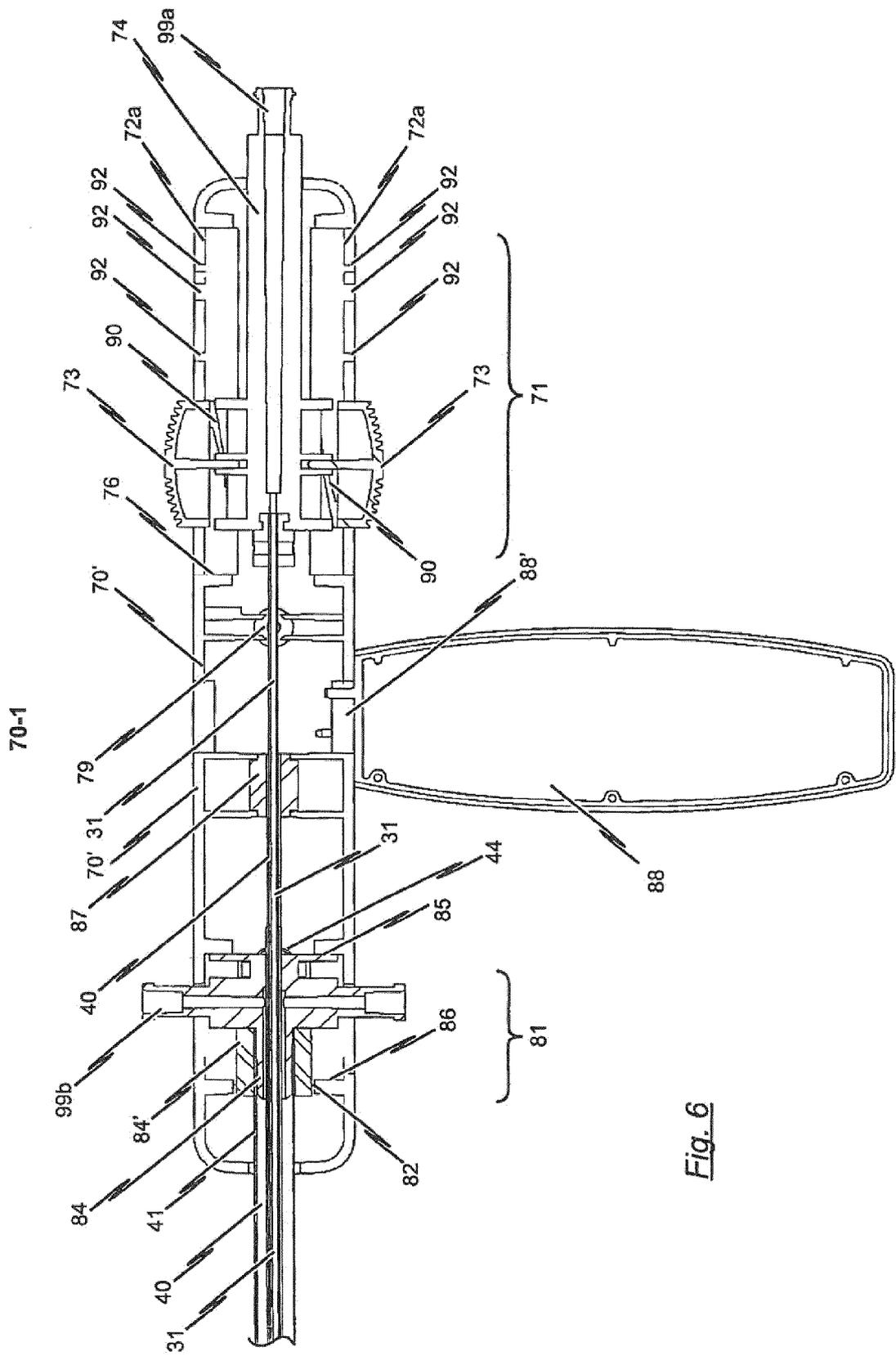
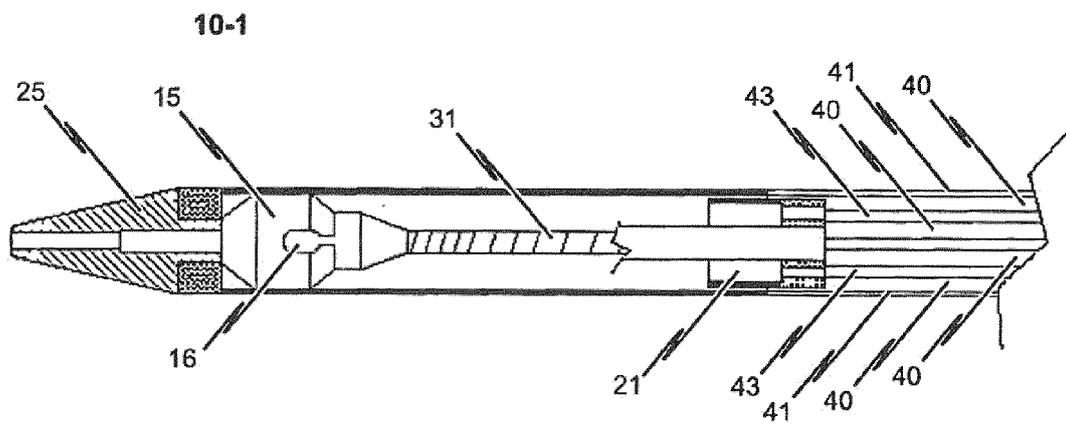
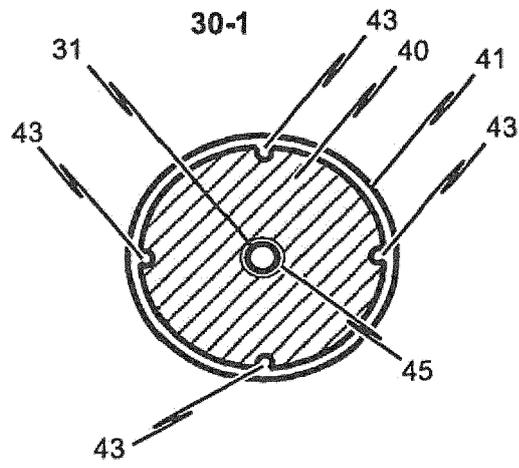


Fig. 6

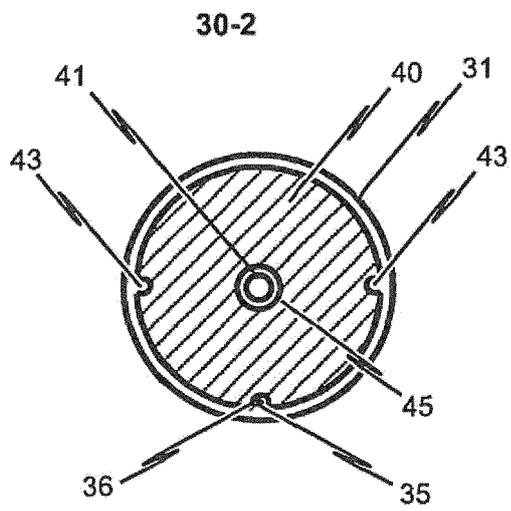




*Fig. 8*



*Fig. 9*



*Fig. 19*

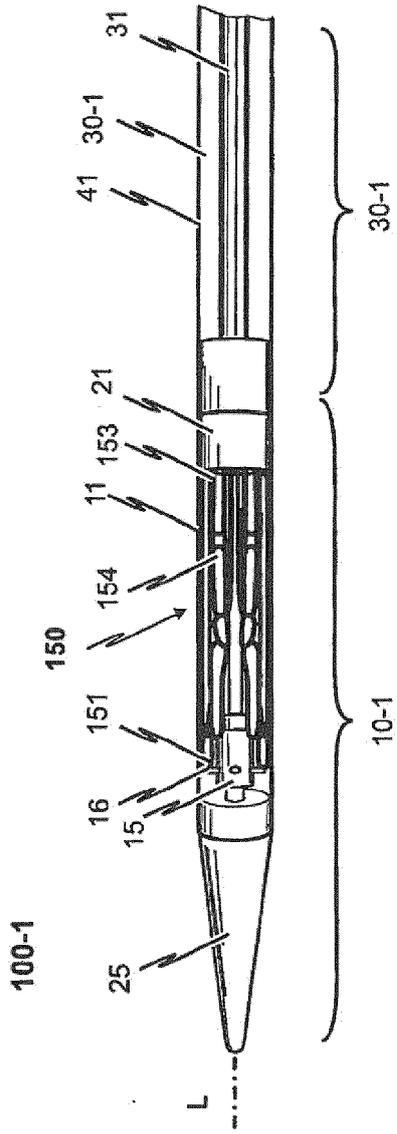


Fig. 10a

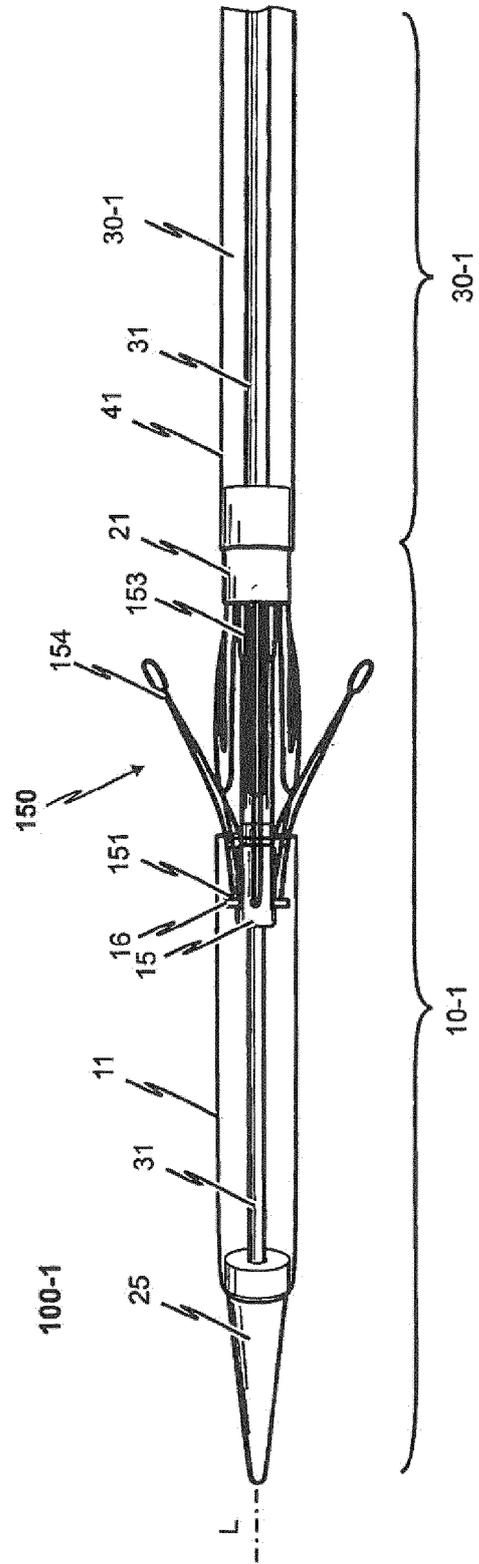


Fig. 10b

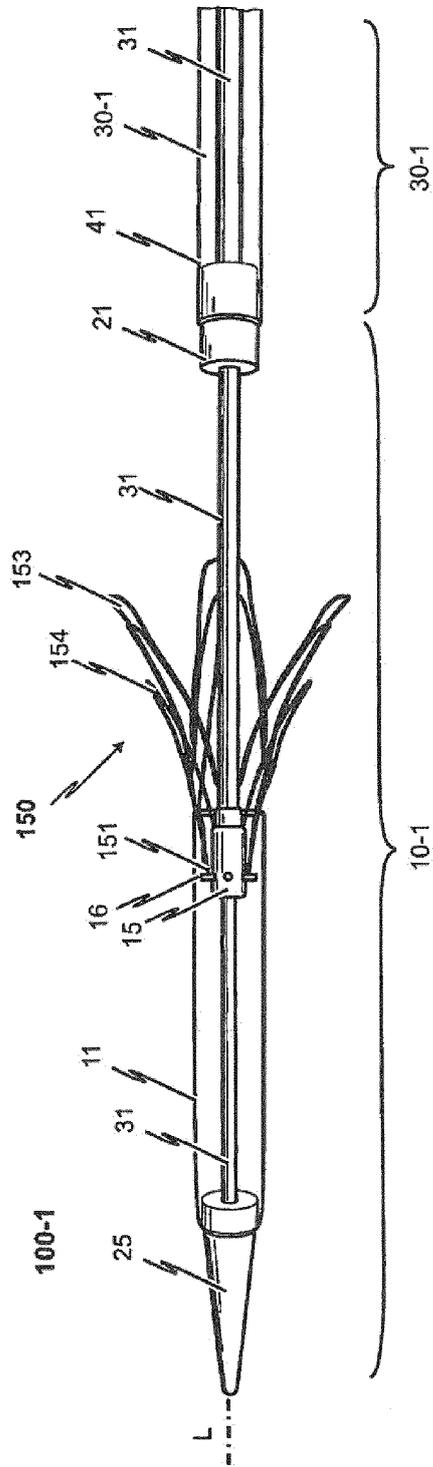


Fig. 10c

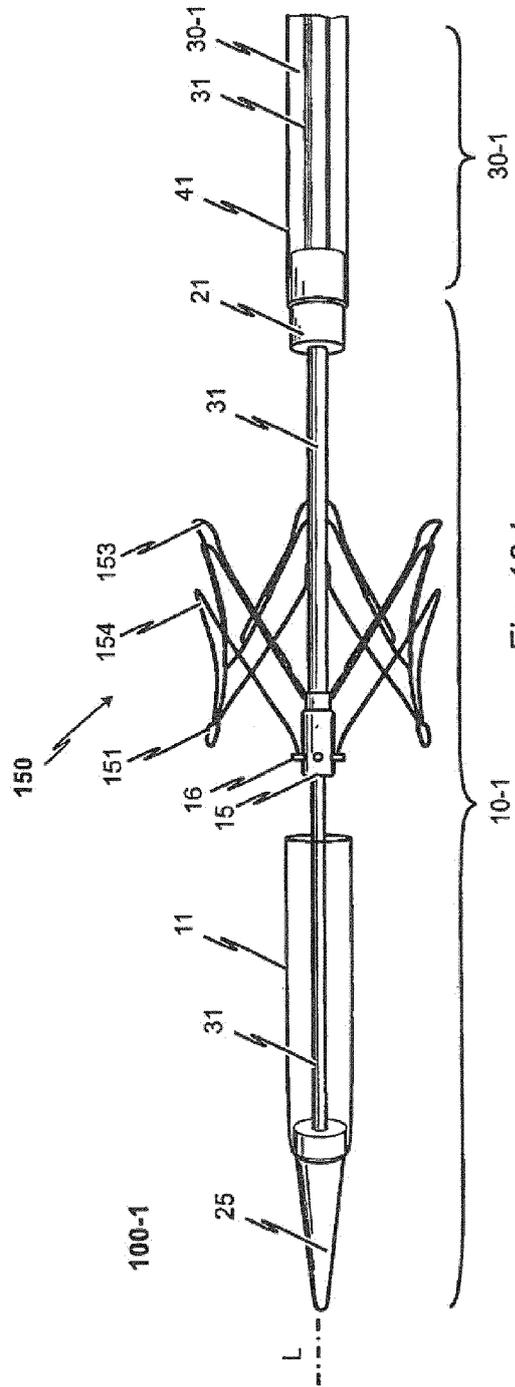


Fig. 10d

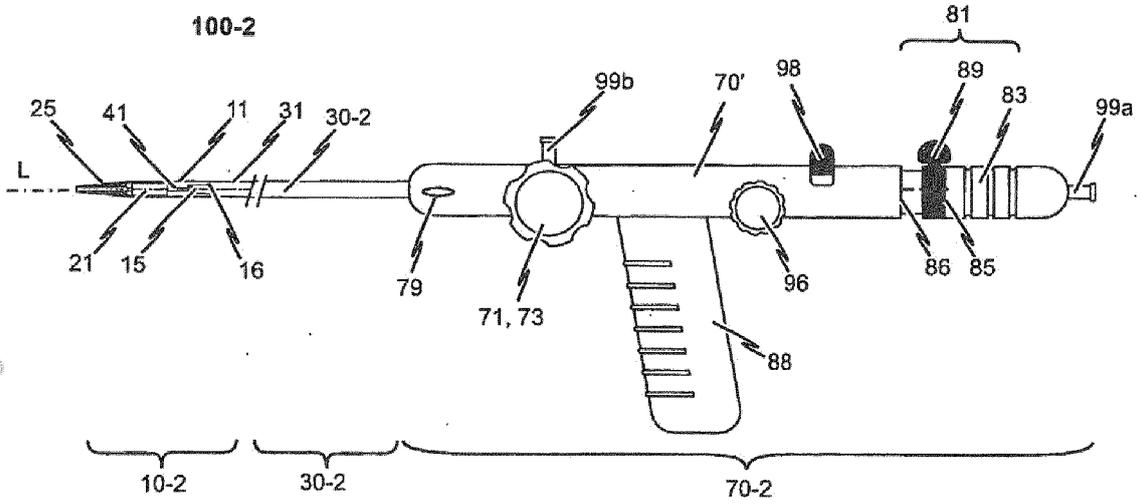


Fig. 11a

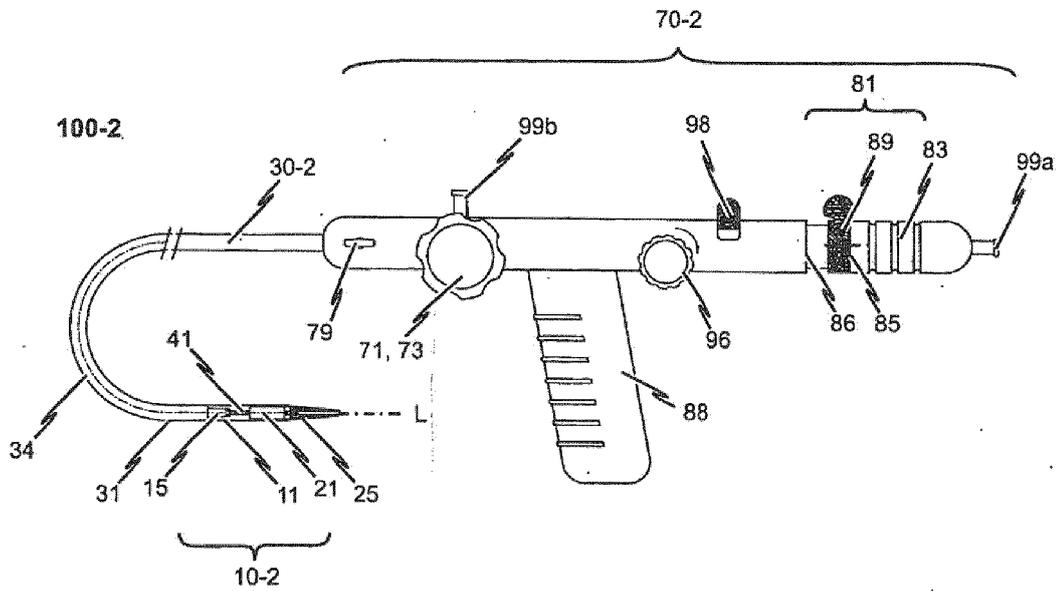
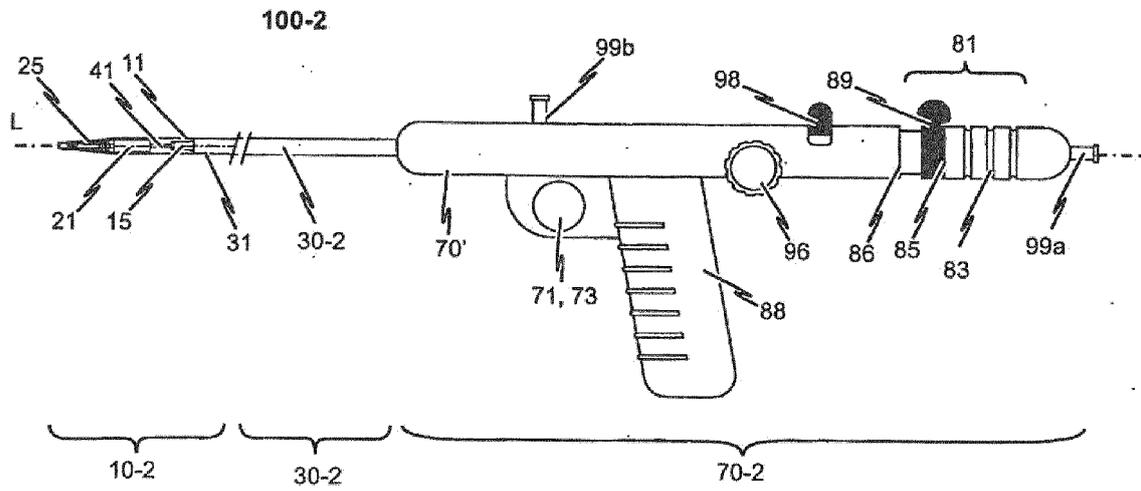
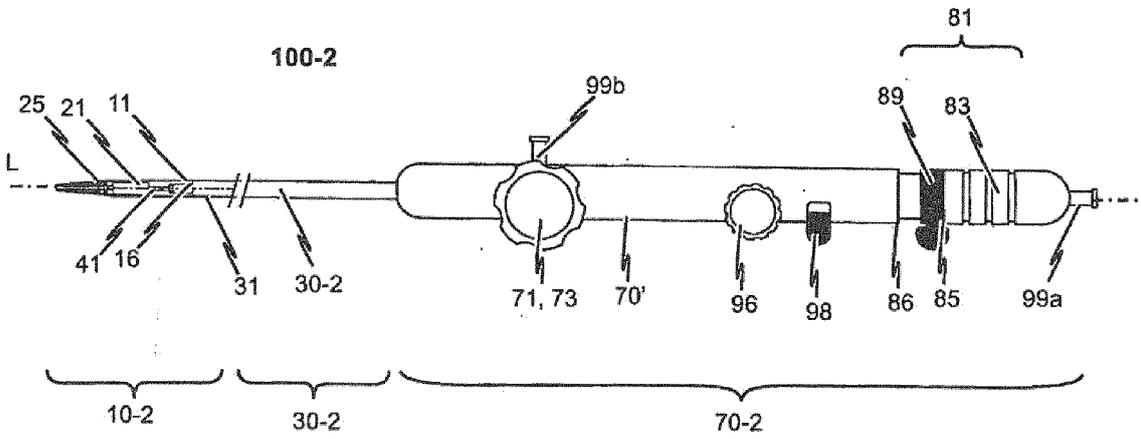


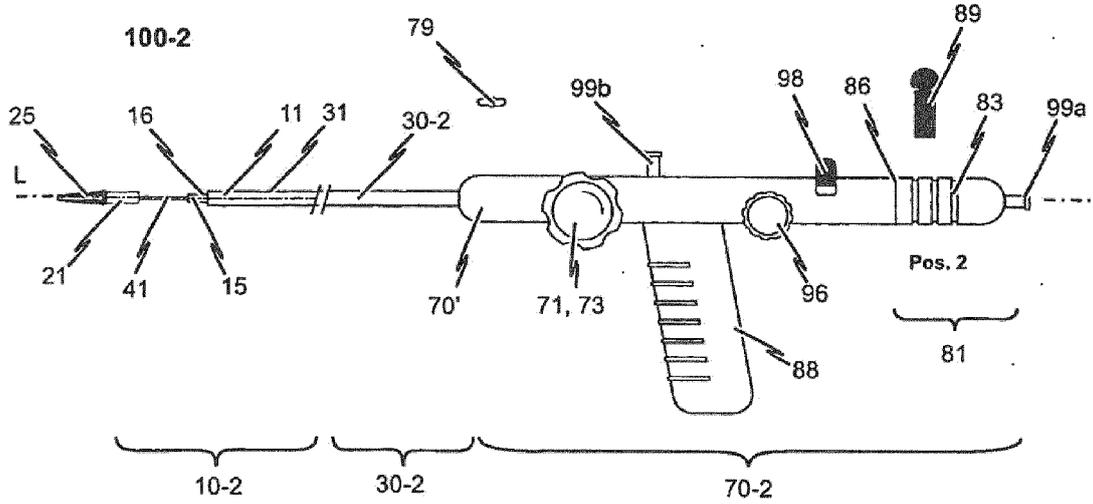
Fig. 11b



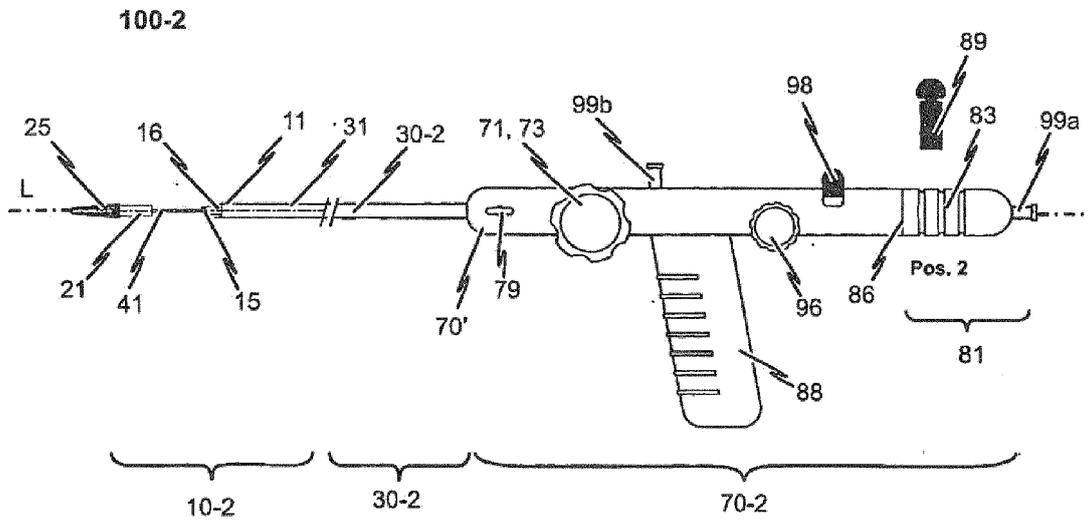
*Fig. 12*



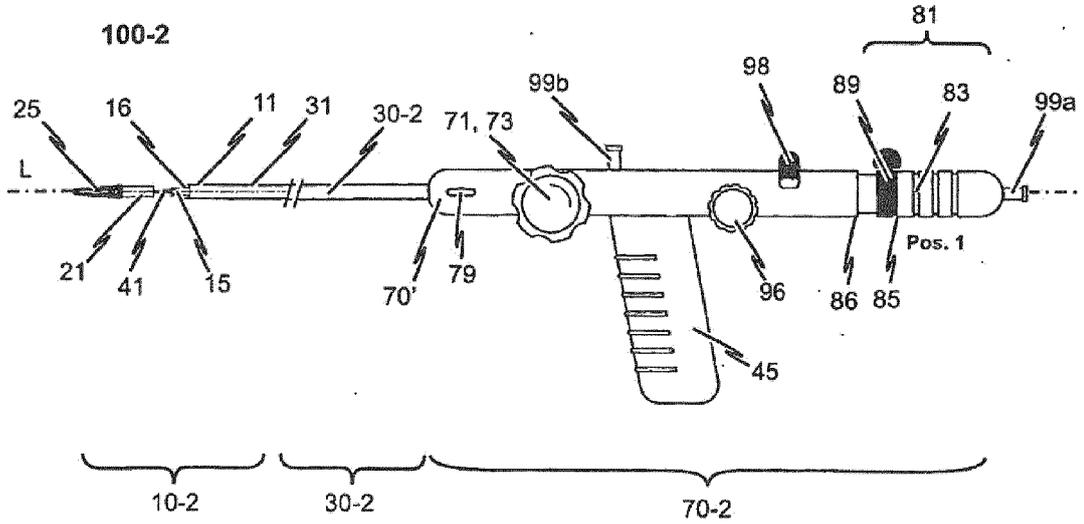
*Fig. 13*



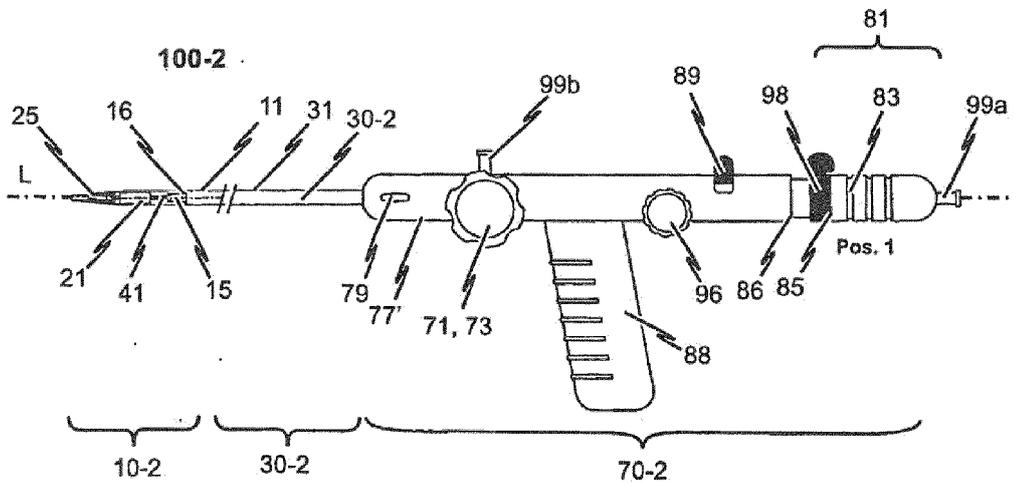
*Fig. 14a*



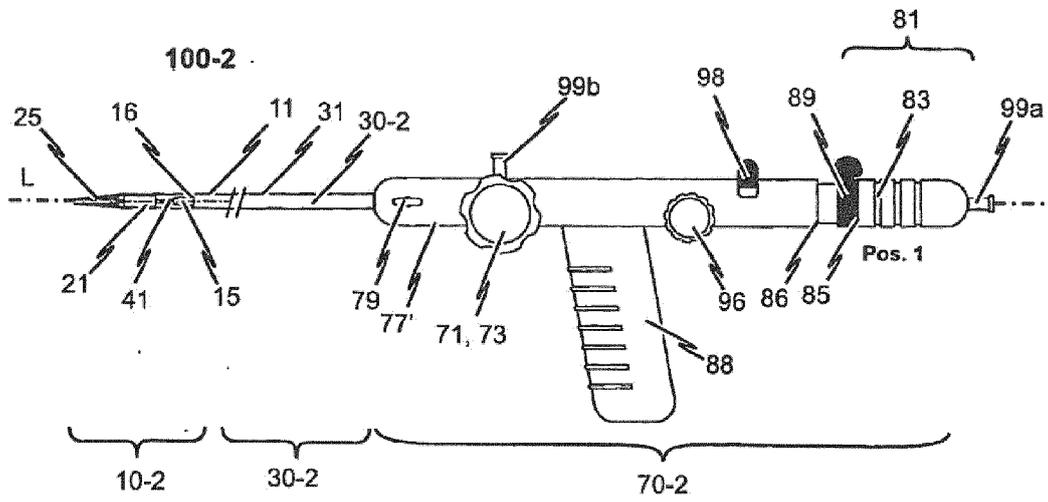
*Fig. 14b*



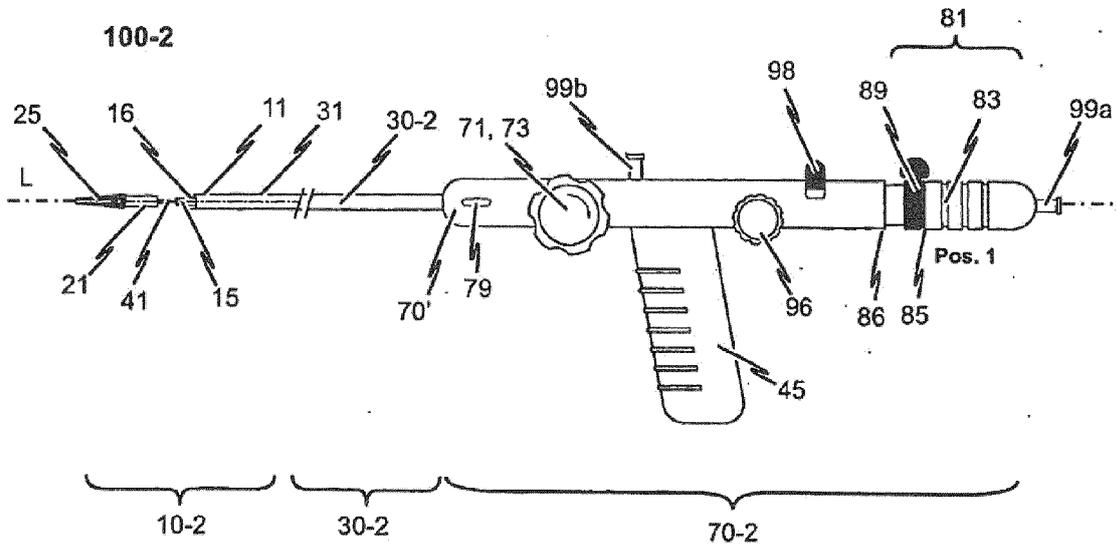
*Fig. 14c*



*Fig. 14d*



*Fig. 15a*



*Fig. 15b*

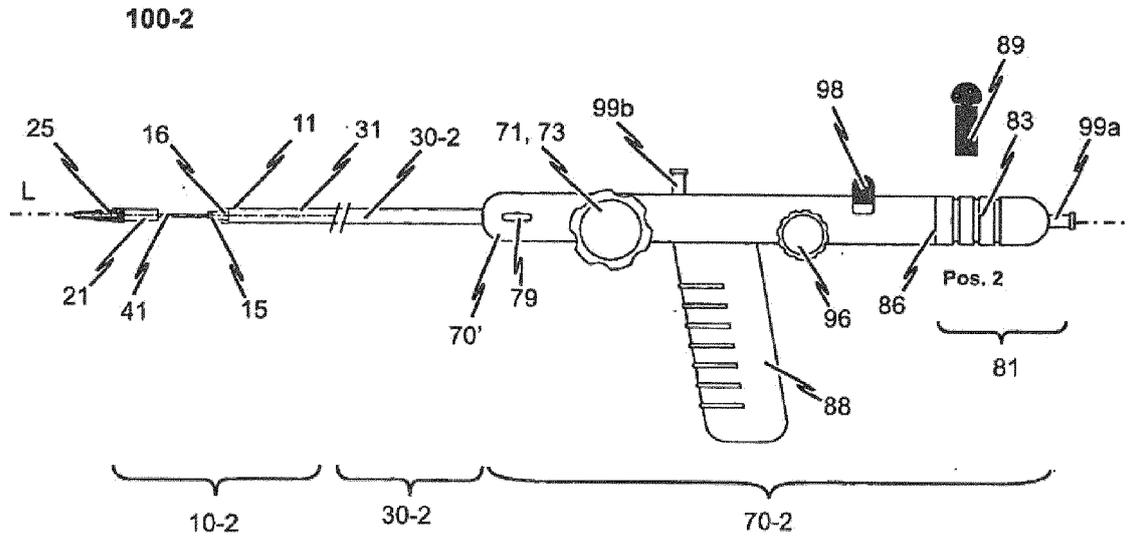


Fig. 15c

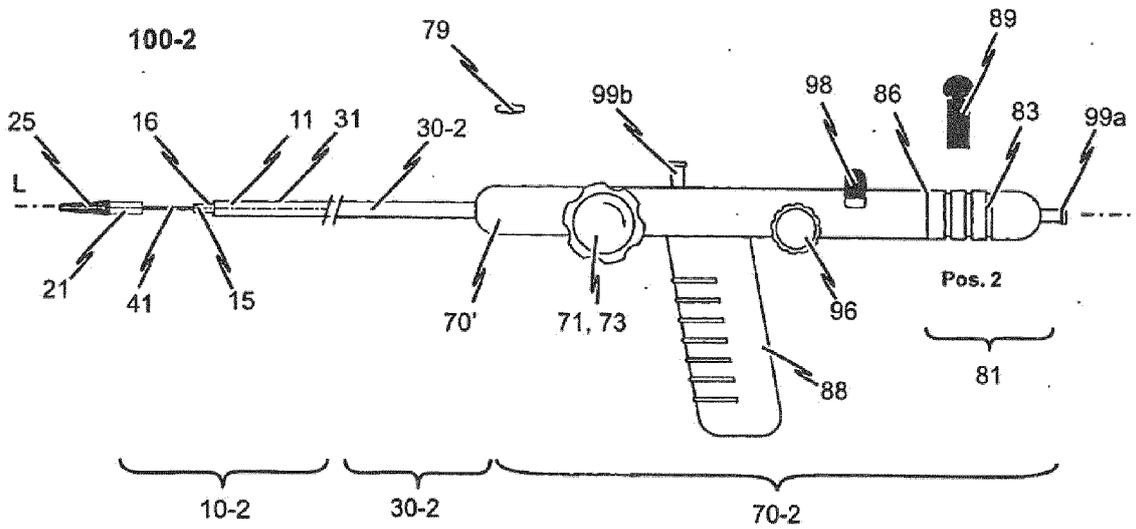


Fig. 15d

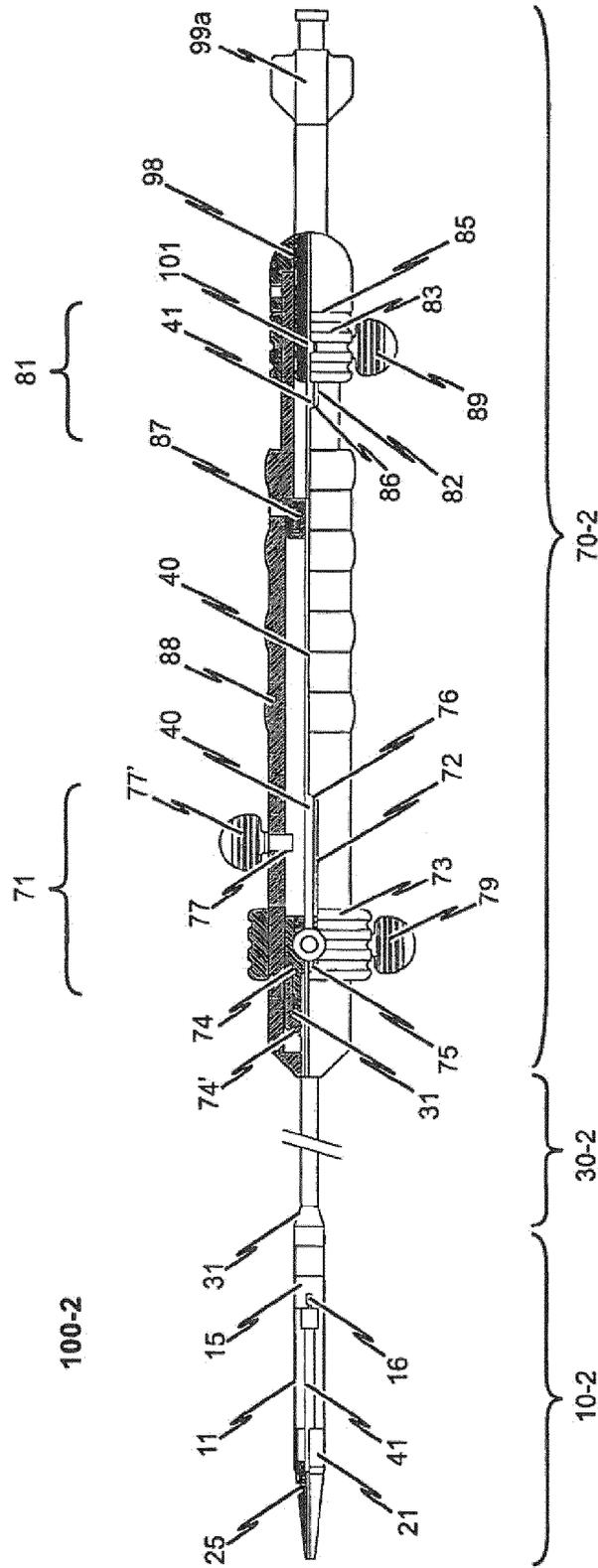


Fig. 16

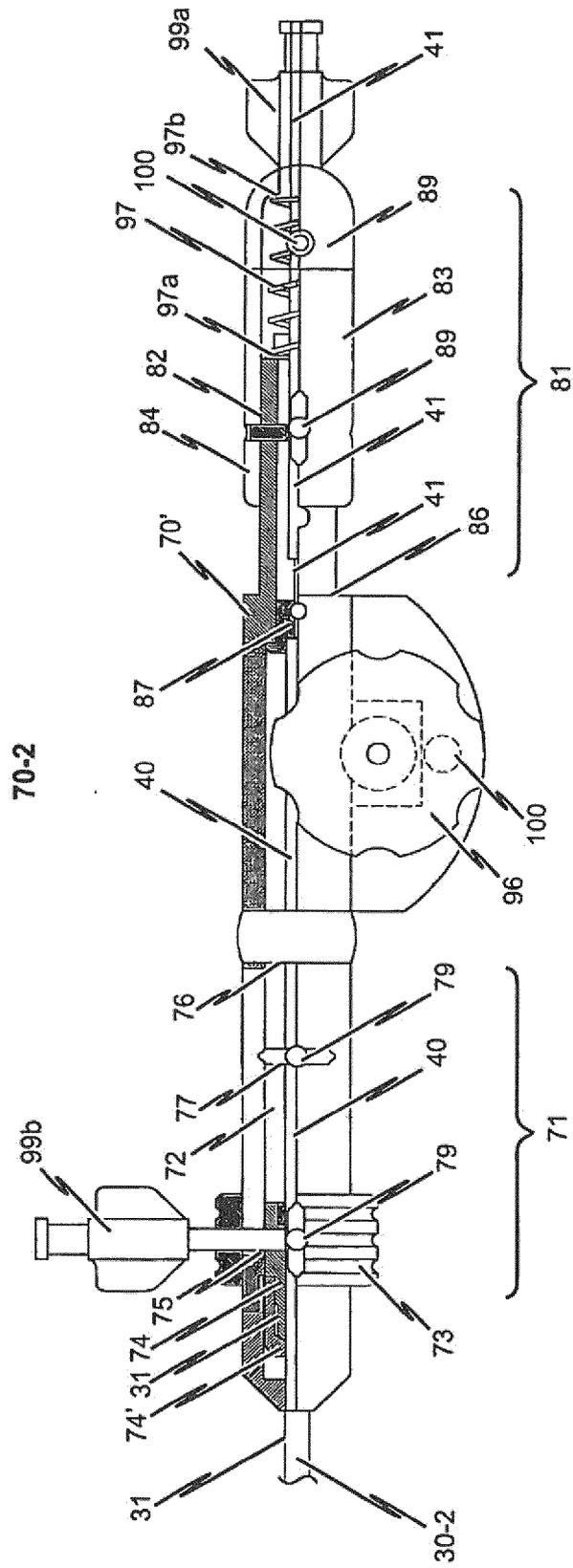
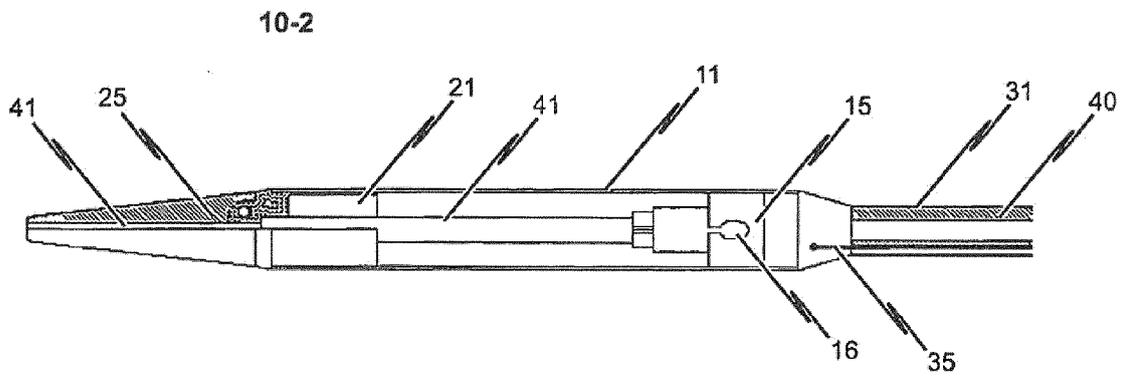


Fig. 17



*Fig. 18*

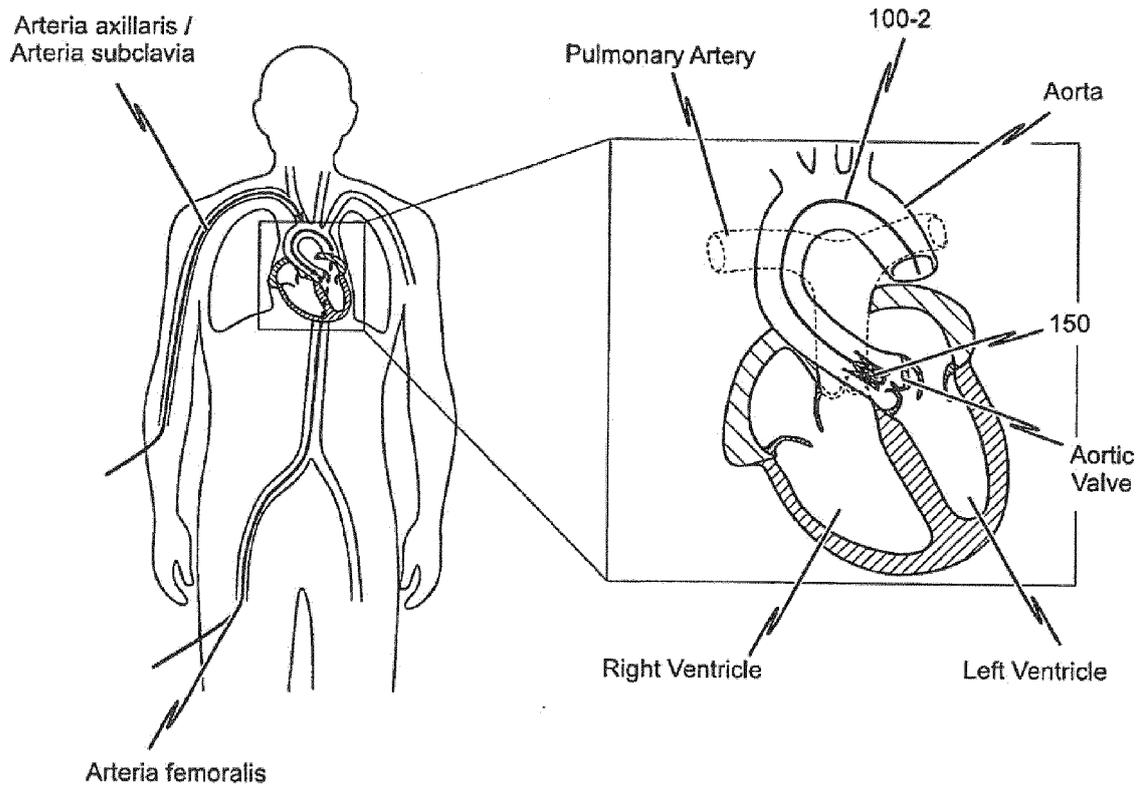


Fig. 20

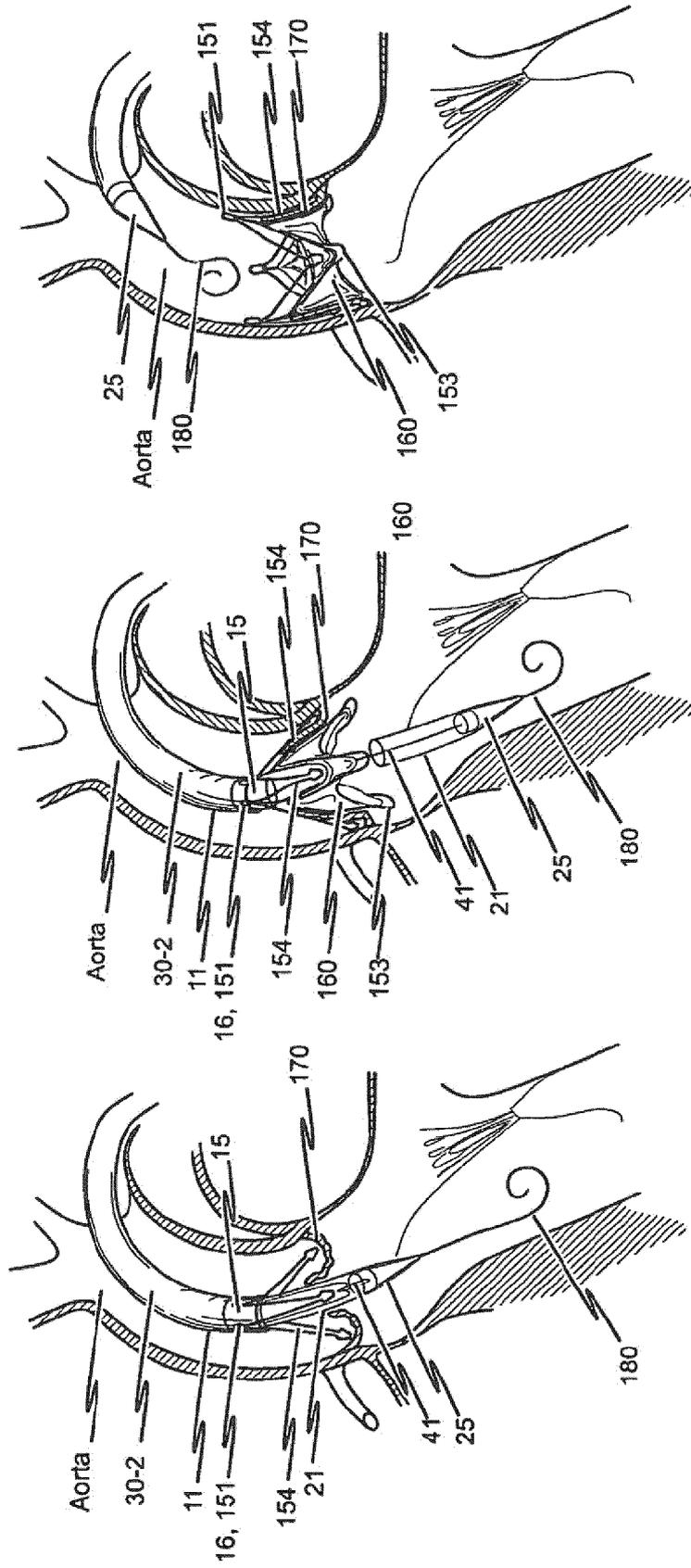


Fig. 21a

Fig. 21b

Fig. 21c



EUROPEAN SEARCH REPORT

Application Number  
EP 13 17 8309

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 2004/028399 A (COOK INC [US]; COOK WILLIAM A AUSTRALIA [AU]; COOK WILLIAM EUROP [DK]) 8 April 2004 (2004-04-08) * the whole document * -----	1	INV. A61F2/24
			TECHNICAL FIELDS SEARCHED (IPC)
			A61F
The present search report has been drawn up for all claims			
Place of search Berlin		Date of completion of the search 29 August 2013	Examiner Amaro, Henrique
<b>CATEGORY OF CITED DOCUMENTS</b> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ..... & : member of the same patent family, corresponding document	

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**ANNEX TO THE EUROPEAN SEARCH REPORT  
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EP 13 17 8309

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29-08-2013

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